

**Variability in ultrasound measurement of hyoid displacement and
submental muscle size within and across sessions using two methods
of data acquisition in healthy participants**

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Abstract

Objective: Ultrasound is used increasingly in swallowing research because it can be a non-invasive, repeatable and cost effective measure of swallowing dynamics and rehabilitative effects. However unstable head position and transducer movement while imaging may result in measurement error that is substantive enough to bias research results. This study investigated the variation in measures of hyoid displacement and submental muscle size within and across three sessions using two methods of acquisition.

Methods: Twenty-four healthy participants over the age of 50 attended three sessions. In each session, five dynamic video clips of hyoid movement and five static images of submental muscles were imaged in 2D ultrasound using two acquisition methods. One method involved manual hand-held stabilisation of the transducer and the other method involved a custom-designed stand for stabilisation of the transducer and participant. Hyoid displacement was measured as a percent change between measures made at rest and at maximal excursion. Additionally, cross sectional area (CSA) measurements were made of the paired geniohyoid and the left and right anterior belly of digastric (ABD) muscles at rest.

Results: Out of 720 possible measures of hyoid displacement, 675 measures were analysed. There were no significant order effects of session or trial with changes that were <1% and no greater 4.5% for session and no greater than 1.5% for trial from estimated baseline measures. There was a significant effect of method ($p<.01$), with a systematic decrease in stand measures that were <9.5% and no greater than 16% from estimated baseline measures. Variance was larger across sessions than within

sessions. The stand condition was more variable than the hand-held condition for measures of hyoid displacement.

Out of a total of 2160 possible measures of submental muscle size, 555 measures of geniohyoid and 1408 measures of ABD muscles were analysed. There were no significant order effects of session, trial or method in geniohyoid muscle measures. The estimated order effects of session were <3% and no greater than 13%, and trials were <0.4% and no greater than 0.7% from estimated baseline measures. There were no significant order effects of session and method in ABD muscle measures with order effects of session that were <2% and no greater than 5.5%. There were significant effects of trial ($p < .01$) in both ABD muscles with a small systematic increase that was <0.5% and no greater than 0.8%. Variance was larger across sessions than within sessions in all measures of submental muscle size. The stand condition was less variable than the hand-held condition for all measures of submental muscle size.

Conclusion: The results from this study provide guidance to researchers who intend to use repeated measures from ultrasound imaging as an outcome measure in swallowing research. The large variability within and across participants in measures of hyoid displacement and geniohyoid muscle size may require further investigation. When the variations described in this current study are considered in the measures of the ABD muscle size then it can be a valuable measure of rehabilitative techniques.

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List of abbreviations

ABD	anterior belly of digastric
CHASE	comfortable head anchor for sonographic examinations
CoV	coefficient of variation
CSA	cross-sectional area
CST	cushion scanning technique
CT	computerised tomography
DICOM	digital imaging and communications in medicine
EMA	electromagnetic articulography
EMMA	electromagnetic midsagittal articulometry
EPG	electropalatography
HATS	head and transducer support system
HOCUS	Haskins optically corrected ultrasound system
ICC	intraclass correlation coefficient
MRI	magnetic resonance imaging
RC	repeatability coefficient
REML	restricted maximum likelihood
VFS	videofluoroscopy

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Chapter 1 Introduction

Ultrasound is used increasingly in swallowing research because it is a non-invasive, repeatable and cost-effective method that can image swallowing dynamics and has the potential to be used as an outcome measure of rehabilitative effects. It has been used to examine swallowing physiology and pathophysiology since the late 1970's and 1980s (Chi-Fishman, 2005). Initially ultrasound studies involved qualitative observations but as technology improved and methodological innovations were made, more quantitative assessments could be achieved (Chi-Fishman, 2005).

A possible methodological issue that has arisen is the manual handling of the ultrasound transducer during imaging. Unstable head position and transducer movement may result in measurement error that is substantive enough to bias research results. Some studies of swallowing behaviour using ultrasound imaging to investigate tongue movement have developed various techniques to stabilise the transducer and/or head of the participant (Carmichael, 2004; Peng, Jost-Brinkmann & Miethke, 1996; Stone & Davis, 1995). Stabilisation has also been used in studies of hyoid movement during swallowing (Chi-Fishman & Sonies, 2002a, 2002b). However, no study has adequately investigated stabilisation against manually held methods during repeated measures of hyoid movement both within and across sessions.

Some studies have suggested that ultrasound imaging could be used to measure the cross sectional area measures of muscles in the body (Chi-Fishman, Hicks, Cintas, Sonies & Gerber, 2004; Pillen, Arts & Zwarts, 2008; Sipila & Suominen, 1991, 1993; Walker, Cartwright, Wiesler & Caress, 2004; Watkin, Diouf,

Gallagher, Logeman, Rademaker & Ettema, 2001). It is possible to image some the floor of mouth muscles involved in swallowing such as the anterior belly of the digastric muscles, mylohyoid and geniohyoid muscles (Emshoff, Bertram, & Strobl, 1999; Jain, 2008, Watkin et al., 2001; Shawker, Sonies & Stone, 1984). Measurement of these muscles could be used as an outcome measure of rehabilitative effects. Only one study has been identified as measuring repeated cross-sectional dimensions in muscles of the head and neck (Emshoff et al., 1999). However this study made only one measure of the muscle that was repeated only once in an interval of at least five minutes using a manually held transducer. No study has adequately investigated stabilisation during repeated measures of cross-sectional area measurements of floor of mouth muscles both within and across sessions.

This study evaluated the variation within participants in ultrasound measures of hyoid displacement and submental muscle size within and across three sessions using two methods of data acquisition, namely using an ultrasound transducer that was either hand-held or stabilised in a custom designed stand. Findings provide information on optimal measurement practices when using neuromuscular ultrasound as an outcome measure of rehabilitative effects.

To help readers gain a better understanding of ultrasound, a brief history on the development of ultrasound and a summary of the physics involved in producing ultrasound images has been included at the start of the literature review. The literature review also covers the advantages of ultrasound imaging compared to other imaging modalities used in investigating swallowing physiology. The literature review then follows onto an overview of ultrasound in swallowing research, particularly in research regarding hyoid dynamics and measurement of swallowing muscles. It

concludes with an examination of the different methods used to stabilise the transducer and/or participant to avoid movement effects before discussing aims and hypotheses.

Chapter 2 Literature Review

2.1 Brief history on development of medical ultrasound

The development of medical ultrasound has progressed through a large international effort from many different people in many different fields, particularly in the last 50 years. However, its beginnings were much earlier. The discovery of the piezoelectric effect and its reverse effect in 1880 by the Curie brothers allowed for the production and transmission of ultrahigh frequency sound waves (Kane, Grassi, Sturrock, & Balint, 2004; Szabo, 2004; Woo, 2008). The piezoelectric effect describes the ability of certain materials such as quartz and ceramics to produce an electrical voltage when mechanical pressure is applied; the reverse effect causes the crystals to deform and resonate when voltages are applied (Mann, 2008; Merton, 1997). This discovery formed the basis of all future ultrasound transducer technology in which a sound burst is sent out and its echoes are received back by the same piezoelectric crystals (Bressmann, Heng, & Irish, 2005; Szabo, 2004).

Initially the discovery was developed for echo ranging in water. This became fully utilised in World War II to detect submarines and became known as sonar (sound navigation and ranging) (Kane et al., 2004). Another form of pulse-echo ranging was also developed during World War II utilising electromagnetic waves called radar (radio detection and ranging). At this time, ultrasonic techniques were being

developed to detect flaws in metals and many industrial devices were manufactured (Kane et al., 2004).

Using knowledge gained from sonar and radar, a number of different researchers from different countries began to investigate medical uses for commercially available industrial ultrasound devices (Kane et al., 2004; Shung, 2006, 2010). The first medical applications of ultrasound were therapeutic, utilising its heating and disruptive ability on tissues when applied at high intensities (Stone, 2005; Woo, 2008). The Dussik brothers, one a neurologist and the other a physicist, are credited for performing the first diagnostic application in 1942 to examine the brain and ventricular system (Kane et al., 2004; Mann, 2008; Merton, 1997).

A form of visual analysis using an oscilloscope screen was developed in 1949. This most basic form of visual analysis became known as Amplitude mode (A-mode) ultrasound (Merton, 1997). It uses a single transducer to transmit and receive echoes. Information is displayed as a one-dimensional scan with depth or time on the horizontal axis and amplitude on the vertical axis (Merton, 1997).

In 1951, the first prototype, B-mode (brightness mode) scanner was developed (Merton 1997, Shung, 2006). B-mode ultrasound displays only the tip of the spike of the A-mode image as a dot on screen. This allowed for two-dimensional imaging in which many B-mode dots were combined and displayed collectively to form an image on the screen (Merton, 1997). Early B-mode ultrasound images were bi-stable (all echoes were displayed as white on a black background).

From the late 1950's, M-mode and Doppler ultrasound were also developed. In M-mode (motion mode) a row of identical crystals emits a sequence of A-mode pulses and the returning echoes are displayed as a time-motion waveform. Continuous

wave and pulsed wave Doppler ultrasound were developed to measure blood flow. It achieves this by comparing changes in transmitted frequency to received frequency that occurs when a transmitted signal hits a moving structure such as blood cells (Merton, 1997). Dual element transducers are required in which one crystal transmits at a known frequency and the other crystal receives the changed signal (Merton, 1997).

Widespread clinical use of ultrasound was not possible until the beginning of the 1960's when commercial units became available specifically for medical applications (Merton, 1997). However it was in the 1970's that ultrasound had a clinical boom period (Merton, 1997; Shung, 2006; Woo, 2008). The introduction of a scan converter and other advances in signal processing allowed for grey scale imaging of the signal's intensity (Merton, 1997). Grey scale imaging significantly improved the diagnostic use of ultrasound. Initially only a few shades of grey were available and as more sophisticated grey scale units developed the contrast resolution and image quality significantly improved (Merton, 1997; Shung, 2006).

Later in the 1970's, technology had advanced enough for real-time imaging (Mann, 2008; Merton, 1997). Real-time imaging is based on a rapid update of image data at a rate of 16 images per second to demonstrate motion (Merton, 1997). Non-invasive real-time imaging became a distinguishing feature of ultrasound against other imaging modalities (Merton, 1997).

The late 1970's and early 1980's lead to operator adjustable mechanical or electronic focussing of the beam, which improved image resolution (Merton, 1997). Smaller hand-held transducers replaced static arm scanners; annotation graphics and on-board measurement capabilities were added (Merton, 1997). Medical applications

were expanding, including the examination of swallowing behaviour (Chi-Fishman, 2005).

The field of ultrasound is constantly evolving and is still making technological advances (Shung, 2010). Recent technical advances have been in the development of colour flow ultrasound, multidimensional imaging (3D and 3D in real time called 4D), the introduction of non-toxic contrast agents, higher frequency imaging (around 20MHz), and portable, pocket-sized scanners (Shung, 2006, 2010).

From its early beginnings in sonar and industrial applications, ultrasound has now become established as a diagnostic tool that is the second most used clinical imaging modality after conventional x-ray (Shung, 2010). It is increasingly being applied in swallowing research to examine both swallowing physiology and pathophysiology (Chi-Fishman, 2005; Mann, 2008; Walker, 2004). While it has many advantages certain limitations, such as not being able to simultaneously view the multiple phases of the swallowing act and the inability to determine pre-swallow spillage, post swallow residue and aspiration (Chi-Fishman, 2005; Sonies, Chi-Fishman, & Miller, 2003), restrict it from being a stand-alone clinical diagnostic tool for swallowing behaviours (Chi-Fishman, 2005). However when available and with adequate training of its use it presents itself as a valuable adjunctive diagnostic tool. If methodological issues are addressed it has the potential to be a repeatable, non-invasive measure of rehabilitative effects (Chi-Fishman, 2005).

2.2 The physics behind ultrasound imaging

Ultrasound refers to extremely high frequency sound waves beyond the range of normal human hearing (Stone, 2005; Watkin, 1999). When using ultrasound

clinically and in research a good understanding of sound wave physics and its effect in various media are required to accurately image and interpret the results (Coltrera, 2008, Hendee & Ritenour, 2002; Sonies et al., 2003; Tole, 2005). The following sections describe the basic physics involved in image formation and how it affects image resolution.

2.2.1 Image formation

Ultrasound imaging uses the pulse-echo principle (Martin, 2010). An ultrasound transducer contains multiple piezoelectric elements that each send out a short burst of high frequency sound energy called an ultrasound beam (Stone, 2005; Watkin, 1999). The piezoelectric elements then switch to a longer listening phase to receive and detect the transmitted sound when it is reflected back from the different media in the beam path (Tole, 2005; Shawker et al., 1984; Walker, 2004; Walker et al., 2004). The signals received are converted into electrical signals that undergo complex computer analysis and processing before an image is reconstructed and displayed on the screen of the ultrasound instrument (Stone, 2005; Tole, 2005; Walker et al., 2004). Echoes that return earlier are from the superficial structures and echoes that return later are from the deeper structures (Walker, 2004).

A B-mode image is formed from the combination of the signals received from multiple pulse-echo sequences from multiple piezoelectric elements (Martin, 2010). It produces a cross-sectional image that generally represents the anatomy of the tissues and organs being scanned (Martin, 2010). Each echo is displayed at a point in the image with the brightness of the image relating to the amplitude (strength) of the reflection (Martin, 2010).

The amplitude of the echo is generally determined by two factors: time-gain compensation and the strength of the reflection (Walker, 2004). As an ultrasound beam travels deeper into a medium it loses intensity through processes of attenuation such as reflection, scattering, refraction, beam divergence, and absorption (Heggie, Liddell, & Maher, 2001; Martin & Ramnarine, 2010). As the intensity decreases so does the amplitude (Martin & Ramnarine, 2010). To compensate for loss of intensity at greater depths, the signals from greater depths are amplified through time gain compensation (Coltrera, 2008; Martin, 2010; Stone, 2005; Walker et al., 2004). Most imaging systems apply a constant rate of compensation to allow for the loss of energy and also allow for operators to make additional adjustments (Martin, 2010). However, inappropriate time gain compensation can cause dark or bright bands of echoes across uniform tissue (Martin, 2010).

The strength of the reflections depends on the acoustic and reflective properties of the media being imaged. Echoes are formed from reflections of the sound wave at tissue boundaries of different acoustic impedance (Martin, 2010; Walker et al., 2004; Watkin, 1999). Acoustic impedance is described as the measure of resistance of the molecules in the media to the transmission of sound based on the density and propagation velocity (or speed of sound) in the medium (Tole, 2005).

When the two media vary greatly in impedance such as soft tissue-to-air and soft tissue-to bone interfaces there is a greater bias towards reflection rather than transmission (Heggie et al., 2001; Stone, 2005). A near total reflection such as at the soft tissue and air interface leaves no acoustic energy to left to travel deeper in to the area of interest (Martin & Ramnarine, 2010; Tole, 2005). An acoustic coupling gel is applied to the edge of the transducer to smooth out the different acoustic impedances

between the transducer, atmospheric air, and skin to allow for sound propagation through the body (Martin & Ramnarine, 2010; Tole, 2005).

When the dimensions of the interfaces are smooth and larger than the wavelength then reflections called specular reflections occur (Heggie et al., 2001). Specular reflections are governed by the laws of reflection in which the angle of reflection is equal to the angle of incidence (Heggie et al, 2001; Martin & Ramnarine, 2010). The axis of the transducer should be perpendicular to the structure of interest to enable the reflection to be directed straight back to transducer (Stone, 2005; Walker, 2004).

High amplitude echoes are formed from specular reflections. They are described as being hyperechoic (Heggie et al., 2001; Watkin, 1999). Bone is hyperechoic; it typically produces a bright echo with dark shadowing behind it because it reflects and absorbs most of the sound energy leaving no energy to penetrate deeper (Walker, 2004; Walker et al., 2004). Smaller bones (for example the hyoid bone) may only be apparent by the large shadow they create (Walker, 2004).

When the boundary is smaller than the wavelength or has a rough surface then the ultrasound wave is scattered in all directions (Heggie et al., 2001; Martin & Ramnarine, 2010). Low amplitude echoes are formed because only some of the energy makes it back to the transducer from the scattered reflections (Heggie et al., 2001; Tole, 2005). The multiple diffuse reflections produce the grey speckle patterns seen in ultrasound images (Coltrera, 2008; Sonies et al., 2003; Watkin, 1999).

Muscles contain many more scatters than specular reflections (Heggie et al., 2001). They are described as being hypoechoic because most of the sound energy is transmitted through with minimal reflection (Heggie et al., 2001; Walker, 2004). It

can be difficult to image muscles individually when they overlap because of similar architecture. Different quantities and arrays of fibrous tissue particularly collagen fibrils within muscles can help differentiate the muscles by making them appear more or less echogenic (Walker et al., 2004). Fibrous tissue tends to be slightly more hyperechoic (Walker, 2004; Walker et al., 2004). In a sagittal image, parallel hyperechoic strands are produced because fibrous tissue tends to be arranged linearly (Walker, 2004). The tongue tends to be slightly hyperechoic overall because of the random orientation of the multiple fibres within the muscle (Walker, 2004; Walker et al., 2004). Muscle contraction and increased muscle size due to exercise can slightly reduce echogenicity due to the small reduction in the ratio of fibrous tissue compared to muscle tissue (Walker, 2004; Walker et al., 2004).

When imaging muscles it is helpful to include sections of other tissues to enable differentiation of muscle (Walker et al. 2004). Superficial dermal tissues are separated from deeper tissue by a thin layer of subcutaneous fat (Walker, 2004). The dermal tissues tend to be denser and more uniform (Walker, 2004). However, fat can affect the echogenicity of deeper muscles because it absorbs and scatters sound (Walker, 2004; Walker et al., 2004).

2.2.2 Image resolution

The physics described above only provide a brief outline on the complex physics involved in forming an ultrasound image. Users of ultrasound also need to be aware of factors that can affect image resolution. These include factors such as the frequency of the beam, beam focussing, alterations in the speed of sound, and refraction of the sound wave.

Frequency determines both axial and lateral resolution of the image (Coltrera, 2008; Kossoff, 2000; Martin & Ramnarine, 2010; Stone 2005). Axial resolution is the ability to distinguish between echoes originating from two reflectors lying behind one another and could also be described as depth resolution (Heggie et al., 2001; Stone, 2005). It is based on the wavelength of the beam (Shung, 2006). Higher frequencies decrease the wavelength providing better axial resolution (Stone, 2005; Walker, 2004). Lateral resolution is the ability to distinguish between echoes originating from two reflectors lying side-by-side perpendicular to the axis of the beam (Stone, 2005). It is based on the transducer beam width (Shung, 2006; Stone, 2005). Higher frequencies have a smaller beam width. The beam is unable to resolve objects smaller than its width and smaller objects will appear to be the same size as the beam width causing phenomena called 'smear' (Martin, 2010; Stone, 2005). While it would make sense to increase frequency to obtain better resolution there is a trade-off with depth penetration (Heggie et al., 2001; Stone, 2005). As frequency increases so does attenuation (loss of sound energy) limiting the amount of depth penetration (Shung, 2006; Stone, 2005).

As sound propagates out of the transducer, an ultrasonic beam pattern is formed with a near and far field and a focal zone in the middle, as displayed in Figure 1 (Heggie et al., 2001; Kossoff, 2000; Stone, 2005). Past the focal zone the ultrasound beam diverges with increasing distance leading to a decrease in lateral resolution and intensity (Martin, 2010). Beam focussing can improve resolution in the focal zone because focussing narrows the beam. However it limits beam depth and reduces resolution past the focal zone because the beam diverges more rapidly past the focal zone (Heggie et al. 2001; Stone, 2005).

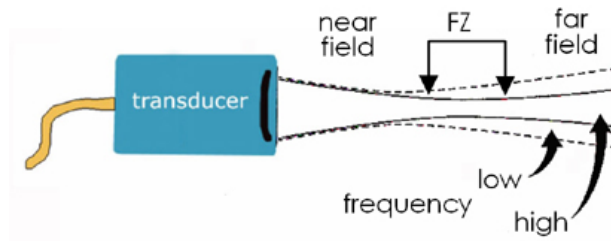


Figure 1. Beam pattern in different frequencies
(source http://www.usra.ca/basic_p)

The speed of sound is used to calculate the distances of the reflected sound waves. Ultrasound machines calculate distances based on the precise timing of the reflected wave using the standard value of 1540m/sec. This value is derived from the average propagation velocity of ultrasound in abdominal soft tissue materials (e.g. fat, liver, kidney, blood, and muscle) as displayed in Figure 2 (Coltrera, 2008; Woo, 2008). Variations in the standard propagation velocity of 1540m/sec, such as bone and fat, can cause imaging errors such as misregistration of targets (resulting in depth errors where the target appears nearer or further away than what it actually is), distortion of interfaces, errors in size, and defocusing of the ultrasound beam (Hendee & Ritenour, 2002; Martin, 2010).

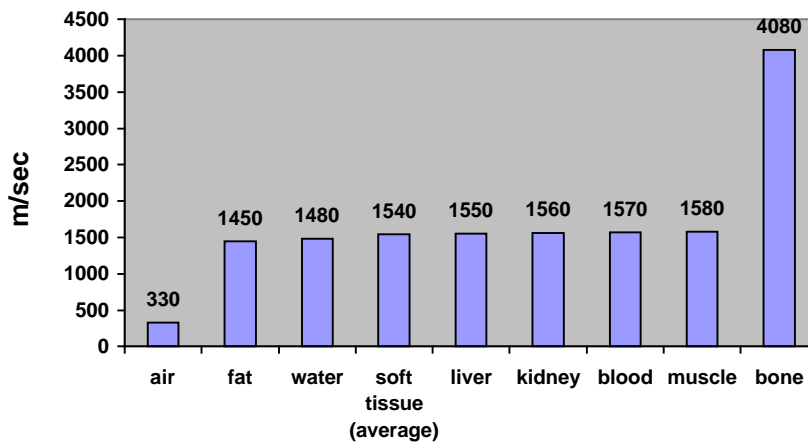


Figure 2. Approximate propagation velocity (speed of sound) of ultrasound in selected materials in the body (source: authors own based on Coltrera, 2008)

Refraction of the beam can also cause some loss of resolution and imaging artefacts such as depth errors (Heggie et al, 2001; Martin, 2010). Refraction occurs when the ultrasound beam obliquely crosses interfaces with different speeds of sound, causing a change in the direction of the transmitted wave from the incidence wave (Kossoff, 2000; Martin, 2010a). Fat and bone can cause considerable refraction and image distortion (Martin, 2010).

When imaging the head and neck users of ultrasound need to make decisions on the selection of imaging parameters. Appropriate time gain compensation needs to be selected to enable correct imaging of deeper structures. Inappropriate selection can have a significant effect on resolution (Martin, 2010). To sufficiently image deeper structures such as the paired geniohyoid muscles, a lower frequency may need to be selected. Appropriate focal zones should be selected that enable the best resolution in the area of interest while also considering the effect of beam divergence past the focal zone on resolution and depth of imaging. Users need to be aware that errors in sound propagation can lead to slight distortions in the image and possible measurement errors (Martin, 2010).

2.3 Ultrasound in swallowing research

Swallowing physiology can be difficult to examine due to accessing and imaging internal structures. Various methods have been employed each with their own advantages and disadvantages. While videoflouroscopic (VFS) imaging is seen as the “gold standard” in swallowing studies it exposes the participant to ionising radiation (Watkin, 1999). Ultrasound is used increasingly in swallowing research because it is a non-invasive, repeatable and cost effective method that can image

swallowing dynamics and has the potential to be used as an outcome measure of rehabilitative effects.

Diagnostic ultrasound presents no potential risks to participants. The acoustic intensity used in diagnostic imaging is not at levels capable of producing harmful thermal effects (Epstein, 2005). Participants can be examined repeatedly and for extended periods of time without any known bio effects (Sonies et al., 2003). Ultrasound does not require the use of contrasting materials such as barium, which may have an effect on swallowing function (Steele, 2005); therefore any type of food can be used in a study (Sonies et al., 2003).

Other imaging methods such as Computerised Tomography (CT) and Magnetic Resonance Imaging (MRI) have been used to visualise muscles (Schedel, Reimers, Nagele, Witt, Pongratz & Vogl, 1992; Sipila & Suominen, 1993) and swallowing (Hartl, Kolba, Bretagne, Bidault, & Sigal, 2010; Panebianco, Ruoppolo, Pelle, Schettino, Roma, Bernardo et al., 2010). Compared to ultrasound, CT exposes the participant to radiation and cannot provide real-time imaging of swallowing and MRI involves a high cost and long acquisition time with difficulties in spatial and temporal resolution (Hartl et al., 2010; Panebianco et al., 2010). Ultrasound is less expensive and more portable than CT and MRI (Chi-Fishman, Hicks, Cintas, Sonies & Gerber, 2004). Once the ultrasound machine has been purchased, data acquisition is relatively quick and inexpensive (Bressman et al., 2005). Examinations using CT and MRI are performed with the participants in a supine position which limits feeding studies (Hiiemae & Palmer, 2003). Ultrasound examinations can be performed with the participant in any position and at bedside if needed (Bressmann et al., 2005).

Other techniques that investigate tongue function such as electropalatography (EPG), electromagnetic articulography (EMA), and electromagnetic midsagittal articulometry (EMMA) have been used in swallowing studies (Chi-Fishman & Stone, 1996). These methods provide some data on swallowing but can only track individual points on the tongue or palate (Stone & Davis, 1995). The receiver coils and wires attached to palates or tongues of participants can make it difficult for the participant to swallow normally (Cheng, Peng, Chiou & Tsai, 2002). The transducer coils can become dislodged or break under the shear forces of bolus propulsion (Hiemae & Palmer, 2003; Steele, 2004, 2005). Costs involved in fabricating individual artificial palates in EPG can be prohibitive (Chiang, Lee, Peng, & Lin, 2003).

Ultrasound is non-invasive and well tolerated by participants of any age (Chi-Fishman, 2005; Mann, 2008; Walker, 2004). It has been used to examine fetal, infant, and adult swallowing behaviour since the late 1970's and 1980's (Abramovich, Garden, Jandial, & Page, 1979; Bowie & Clair, 1982; Chi-Fishman 2005; Marsal, 1983; Shawker, Sonies, Stone, Baum, 1983; Shawker, Sonies, Hall, & Baum, 1984; Stevens, 1978). Initially studies were qualitative but with improvements in technology and if methodological issues are addressed then ultrasound studies can provide important quantitative information (Chi-Fishman, 2005).

2.3.1 Measuring swallowing dynamics through hyoid movement

Ultrasound has been used in a number of different studies to measure swallowing dynamics, such as movement of the tongue (Cheng et al., 2002; Chi-Fishman, Stone & McCall, 1998; Galen & Jost-Brinkmann, 2010; Peng, Miethke, Pong & Lin, 2007; Soder & Miller, 2002); hyoid (Chi-Fishman & Sonies, 2002a,

2002b; Cordaro & Sonies, 1993; Sonies, Parent, Morrish & Baum, 1988; Scarborough, Waizenhofer, Siekemeyer & Hughes, 2010; Yabunaka, Sanada, Sanada, Konishi, Hashimoto, Yatake et al., 2011); laryngeal (Komori, Hyodo, & Gyo, 2007; Kuhl, Eicke, Dieterich & Urban, 2003), and lateral pharyngeal walls (Miller & Watkin, 1997). Movement of the hyoid bone is an important marker of swallowing (Chi-Fishman, 2005; Dodds, Stewart & Logemann, 1990; Ekberg, 1986). Ultrasound cannot directly image the hyoid bone because it is a bony structure surrounded by many, dense muscular, ligament, and tendon connections (Cordaro & Sonies, 1993). However the hyoid bone casts a distinct acoustic shadow that can be tracked during swallowing (Chi-Fishman 2005; Chi-Fishman & Sonies, 2002a, 2002b). The anterior border of the hyoid shadow intersects with the distinguishable geniohyoid and mylohyoid muscles (Shawker, Sonies, & Stone, 1984) creating a tracking reference (Chi-Fishman & Sonies, 2002a, 2002b). During swallowing, the hyoid shadow moves towards the front of the mouth. At the peak of swallowing, the hyoid shadow is typically at its maximal anterior-superior displacement (Chi Fishman, 2005). The hyoid shadow remains at maximal displacement for a short period before returning back towards starting position (Chi-Fishman & Sonies, 2002a, 2002b).

Yabunaka et al. (2011) tracked hyoid movement using a hand-held ultrasound transducer on 30 healthy participants in three different age groups (20-39, 40-59, 60-79 years). Participants were given 5ml of mineral water to rapidly swallow. This procedure was repeated five times for averaging. They suggested that the normal swallow consisted of four phases of hyoid movement. The hyoid bone first rises from its resting position, then moves anteriorly to reach maximum displacement, then remains in a temporary phase, and finally returns to its resting position. Swallowing

duration was tracked from initiation of hyoid movement to return to resting position. They found the total average swallowing duration increased with age although the hyoid remained in the temporary stage for a significantly shorter period in the older age group. They also found a significant difference between the youngest and oldest group in maximal elevation point of hyoid bone movement, which decreased with age.

Using a custom made transducer holder device to stabilise the transducer, Chi-Fishman and Sonies (2002a) examined different discrete (5cc, 10cc, 20cc, 30cc) and rapid sequential (120cc) swallowing tasks with a number kinematic variables. Thirty healthy volunteers were studied using the same age groups as described above. The researchers also found an increase in duration of hyoid movement with increasing age. In contrast to Yabunaka et al. (2011) they suggested there was a systematic increase in maximal amplitude with increasing age; however these age effects were not significant.

Chi-Fishman and Sonies (2002a) also reported that rapid sequential swallowing in normal healthy participants was performed in a shorter duration than discrete swallows of any volume. This was due to reduced range of movement of the hyoid rather than increasing movement speed. However during discrete swallow trials, large volume swallows had greater maximal amplitude of hyoid than smaller volume trials and were completed in a shorter duration of time. They also reported gender effects in which males had significantly higher mean scores for maximal amplitude, total distance and forward peak velocity. Consistently higher but not significant effects of backward peak velocity, time to backward peak velocity and total duration were also reported for males.

Using the same custom made transducer holder as used in their discrete and sequential swallowing study (Chi-Fishman & Sonies, 2002a), Chi-Fishman and Sonies (2002b) examined the effects of systematic bolus viscosity and volume changes on hyoid movement kinematics in 31 healthy participants in the same age groups as reported in the two studies above. They found that the bolus of highest viscosity had the greatest total movement duration and preswallow gesture; larger volume swallows had greater maximal amplitudes, forward peak velocity, and total vertical distance; and older participants had the greater maximal vertical amplitude, backward peak velocity, longer start to maximum duration, and longer total vertical distance. While the older group displayed the greatest overall maximal amplitude this was due to greater vertical movement and not horizontal movement.

Studies of hyoid movement have provided valuable information regarding swallowing dynamics. Some studies have employed manual handling of the transducer (Yabunaka et al., 2011) and others have attempted to control possible movement by stabilising the transducer (Chi-Fishman & Sonies, 2002a, 2002b). However none of the studies have investigated the variability between the methods and the variability of measures over time. As a possible measure of rehabilitative effects, variability of hyoid measures over time would need to be evaluated.

2.3.2 Measurement of floor of mouth muscles

Previous studies have suggested that ultrasound can be used to quantify cross sectional area measurements and tissue composition in various muscles of the body (Chi-Fishman et al., 2004; Pillen, Arts & Zwarts, 2008; Sipila & Suominen, 1991, 1993; Walker et al., 2004; Watkin et al., 2001). When care is taken to avoid

measurement errors, ultrasound measurement of muscles can be reliable (Emshoff et al., 1999; Ishida, Carroll, Pollock, Graves & Legget, 1992; Pillen et al., 2008).

It is possible to image some the floor of mouth muscles involved in swallowing such as the anterior belly of the digastric muscles, mylohyoid and geniohyoid muscles (Emshoff et al., 1999; Jain, 2008; Watkin et al., 2001; Shawker, Sonies & Stone, 1984). Using a submental approach in a coronal plane, the paired muscles of the ABD muscle are identified as two separate oval hypoechoic structures lying superficial to the U-shaped hypoechoic band of the mylohyoid muscle (Emshoff et al., 1999). The mylohyoid is a thin band of tissue connected to the mandibular ramus on each side (Singh, Chin, Chan, Wong, Prasad & Yu, 2010). The paired geniohyoid muscles lie immediately deeper to the mylohyoid muscle, identified as a single hypoechoic structure (Jain, 2008). Refer to Figure 3 for an image of these muscles.

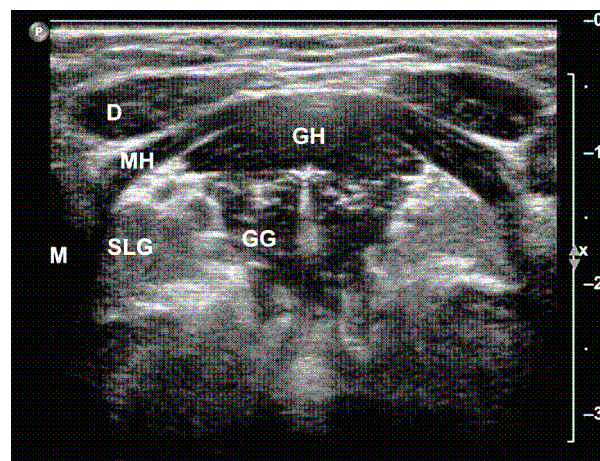


Figure 3. Coronal ultrasound image of the floor of mouth muscles in a 10-year old child. Imaging in children is generally clearer than adult imaging due to less adjacent fat. D, anterior belly of the digastric; GG, genioglossus; GH, geniohyoid; M, mandible; MH, mylohyoid; SLG, sublingual gland (source Jain, 2008, p 101).

Few studies have been undertaken to quantify ultrasound measurement of the cross-sectional area and tissue composition of the floor of mouth muscles. Watkin et

al. (2001) undertook a study to determine if B-mode ultrasound could be used to quantify muscle changes due to age and radiotherapy in cross-sectional muscle area and tissue composition of the geniohyoid muscles. Twelve participants were studied, four normal participants in a younger age group (aged 25 to 28 years), four normal participants in an older group (aged from 64-75 years), and four participants who had undergone radiation therapy for oral pharyngeal cancer. Participants attended one session and performed three repetitions in each of five tasks (a rest gesture, two speech gestures with normal conversational tongue force and two speech gestures with maximal tongue force). Results suggested the patient group had significantly greater cross sectional area compared to the younger group during rest and effortful speech tasks. Variability in tissue composition was significantly greater in the patient group compared to both the younger and older group; variability was also significantly greater in the older group compared with the younger group. The authors suggested ultrasound might provide a method of measuring treatment effects and rehabilitation procedures in head and neck cancer patients (Watkin et al. 2001).

Emshoff et al. (1999) analysed the reliability and variability of linear cross sectional diameter measures of muscles of the head and neck when using B-mode ultrasound. Forty-six patients with signs and symptoms of temporomandibular disorders were measured in two sessions at least five minutes apart. Using the intraclass correlation coefficient (ICC) they found an acceptable intrarater reliability of 0.91 and repeatability coefficient (RC) of 0.48mm in mean measures of the ABD muscles. Acceptable standards were defined as ICCs greater than 0.75 and RCs no greater than 0.50mm. However a method error of 0.36mm (a measure no greater than 0.30mm was considered acceptable) and limits of agreement between 0.97mm and -

0.19mm were reported for these muscles. This suggests some variability between measures in which correlation measures alone maybe misleading in terms of reliability measures. This study only made one measure of the muscle that was repeated only once using a manually held transducer. No study has adequately investigated stabilisation during repeated measures of cross-sectional area measurements of floor of mouth muscles both within and across sessions.

2.4 Stabilisation during ultrasound examinations

While the studies discussed above provide valuable information regarding swallowing physiology using a non-invasive technique some important methodological issues have arisen. Chi-Fishman (2005) reports that in oropharyngeal research using ultrasound the following issues should be addressed: “(1) control of transducer placement, (2) control of head movement, (3) use of a reference system for measurement standardization before cross-subject comparison, and (4) assessment of measurement reliability”. (p. 601). Various techniques have been developed in the field of swallowing and speech research to overcome some of these problems.

The most common method involves stabilisation of the head and/or transducer. Stone (2005) has prepared a comprehensive guide to analysing tongue motion from ultrasound images. The guide discusses the advantages and limitations of a number of different methods to stabilise the head such as using a dental chair and headrest, helmet, cervical collar, or the Head and Transducer Support system (HATS, Stone & Davis, 1995).

The HATS system was developed to stabilise the head and transducer as well as allowing for adequate participant comfort and calibration (Stone & Davis, 1995). It

has been used in a number of ultrasound studies of tongue movement (Chi-Fishman, Stone, & Call, 1998; Hueber, Benaroya, Chollet, Denby, Dreyfus, & Stone, 2010; Li, Kambhamettu, & Stone, 2005). Using an acoustic standoff to prevent tissue compression the transducer holder was validated using videofluoroscopy and was found to be well within measurement error limits (Stone & Davis, 1995). The head holder was validated through lateral videoing of two participants for 20 minutes each. Using two easily identified features of the recordings, the outer canthus (corner) of the eye and lowest most anterior portion of the ear canal, there was virtually no difference in location between frames from the start and end of the video (Stone & Davis, 1995).

The HATS system is quite a large apparatus suitable for research purposes. Hueber et al. (2010), who used the HATS system to collect ultrasound images from two participants, identified several concerns leading to a discussion of future development of a more portable acquisition device. A problem also arose during data acquisition in which accidental displacement occurred with the second participant. Around a quarter of the data that occurred before displacement needed to be discarded from the second participant. A corresponding amount of data was also discarded from the first participant.

Peng, Jost-Brinkmann and Miethke (1996) developed a device called the cushioning scanning technique (CST). It was developed to ensure positional stability during repeated trials and has been used in a number of different studies of tongue movement (Cheng et al., 2002; Chaing et al., 2003; Peng, Jost-Brinkmann, & Miethke, 2000; Peng, Jost-Brinkmann, Yoshida, Miethke & Lin, 2003). The CST comprises of a PVC bag filled with an intravenous injection of water, a transducer holder, a head support for the forehead, and frontal and lateral transparent acrylic

plates to allow for repeated head positioning in the Frankfort horizontal plane. The PVC bag connects to two drainage pipes to ensure constant pressure in the cushion and an even distribution of local pressure from movements of the entire mandible or submental area.

Peng et al. (1996) compared ultrasound images of tongue movements produced using a hand-held transducer with the CST in five healthy participants using real-time B+M-mode ultrasound. They reported the hand-held technique produced vertical and sagittal displacements of the transducer. The duration of a single swallow and range of tongue movement was significantly lower when using the CST compared to the hand-held technique. They concluded that the CST allowed for a more standardised and objective ultrasound examination that was highly reproducible when compared to the more conventional hand-held technique. However in the hand-held technique, the participants rather than the examiner held and positioned the transducer. All participants had difficulty holding the transducer in place and tried to control movement by pressing it harder into the submental area, which may have hindered swallowing.

Cheng et al. (2002) used the CST when examining the relationship between dental facial morphology and tongue function during swallowing in 112 healthy participants. A standard reference material was developed to evaluate the validity of the CST with results indicating a 0.93% distortion. Their results found that during a swallowing cycle, participants ranged from 1.4 to 3.6 seconds for the total duration of tongue movement and from 12.0 to 44.6mm for the total magnitude of motion suggesting considerable inter-participant variability in swallowing patterns. A randomly selected participant was evaluated for intra-individual reproducibility. This

participant was asked to swallow 10 times during the same visit. Results indicated errors of 5.65% in total duration of tongue movement and 3.99% in magnitude of motion measurement. A randomly selected participant was subsequently investigated for intra-examiner errors. Coefficient of variation (CoV) was calculated on 10 repeated measures on the participant by the same examiner 7 days apart. Ultrasound measurement errors were 4.4% in duration, and 1.08 in magnitude.

Peng et al. (2003) used the CST during their study to investigate the difference in tongue movement between infantile and mature swallowing patterns. Coefficient of variation used to calculate ultrasound measurement errors found intra-examiner errors of 2.4% for duration and 1.28% for magnitude in one randomly selected participant. Intra-individual reproducibility on a randomly selected participant performing 10 swallows during the same visit had a CoV of 3.41% for duration and 3.66% for magnitude.

The results above suggest a high intra-individual reproducibility when using the CST. However, Soder and Miller (2002) rejected the CST after undertaking a pilot study in which they suggested the CST would not avoid artefacts. Their pilot study on 8 healthy participants found the CST impeded swallowing and participants complained of discomfort when using the device. They reported no swallowing pattern of tongue movement as claimed by Peng et al. (1996, 2003) with wide variability within and between participants. They decided not to use the CST in their study of intrapersonal variability of tongue movements in 10 normal and 10 individuals with neurogenic dysphagia. They suggested a method of hand-held stabilisation of the ultrasound transducer that provided adequate stabilisation.

Bressmann, et al. (2005) describe another system similar to the CST with a

structured headrest and a stabilised transducer. The Comfortable Head Anchor for Sonographic Examinations (CHASE; Carmichael, 2004) was developed in their laboratory for use on research participants that were mainly head and neck cancer patients. They wanted a device that was comfortable and unthreatening for their participants. They suggested that the device reduced head and transducer movement to an acceptable level, which was described as less than 1.5mm of lateral displacement after 10 minutes of speech recordings.

Chi-Fishman and Sonies (2002a, 2002b) used their own custom-made transducer holder device. Their device allowed for up-down, left-right, and front-back adjustments to provide individualised transducer positioning and stabilisation. This system stabilised the transducer but not the participant's head. The participant's head was secured to the headrest of a dental chair with a soft cloth headband.

Another study (Whalen, Iskarous, Tiede, Ostry, Lehnert-Lehouillier, Vatikiotis-Bateson & Hailey, 2005) suggested that immobilisation of the head or jaw may impede jaw movement and trigger compensatory mechanisms in the tongue. They suggested that immobilisation may restrict the general posture of the person and may affect their natural speech patterns and that certain people may find it difficult to undergo the required immobilisation (e.g. the elderly, children, and people with certain speech disorders). Their study described another system to image the tongue during speech called the Haskins Optically Corrected Ultrasound System (HOCUS). This system incorporates ultrasound imaging and optical tracking of the transducer relative to the head. A camera tracks the motion of infrared probes placed on the transducer and the participant's head. Frames in which the transducer rotated or slid out of plane were identified and corrected or discarded.

In tongue imaging, Whalen et al. (2005) suggested that small translations or rotations out of a midsagittal plane can still be acceptable and data used. They describe acceptable levels of rotations to be less than 5° in the vertical plane (as the average error was at most 0.7mm), less than 5° - 7° in pitch and roll, and lateral translation of 2-4mm. Any deviations above this greatly affected tongue shape and the error became quite large. The HOCUS system is ideal if the goal is to image as close as possible to natural speech conditions but may not be helpful if too much data needs to be discarded.

Gick, Bird and Wilson (2005) discussed the difficulties involved in lingual imaging in the field setting especially in regards to controlling head and transducer movement and limiting tissue compression. They found the greatest head displacement occurred along the y-axis so attempts should be made to limit vertical head movement. Their pilot study suggested that in field studies with limited equipment, resting the participant's head against a surface during data collection might be a simple and effective solution to control head and transducer movement.

While the studies above identify a number of approaches to limit head and transducer movement and tissue compression none have adequately researched the repeatability of the acquisition methods on a number of different participants. To be a valid measure of rehabilitative effects the variability of measurement needs to be examined.

2.5 Aim of study

The aim of this study was to evaluate the variation in ultrasound measures of hyoid displacement and submental muscle size within and across three sessions using

two methods of data acquisition, namely using an ultrasound transducer that is either hand-held or stabilised in a custom designed stand.

2.6 Hypotheses

1. There will be no significant order effects of session, trial or method in measures of hyoid displacement.
2. The intra- and inter-session variability will be similar in measures of hyoid displacement.
3. The fixed-stand method will be less variable than the hand-held transducer method in measures of hyoid displacement.
4. There will be no significant order effects of session, trial or method in 2D cross-sectional area measurements of the paired geniohyoid muscles and the left and right ABD muscles respectively.
5. The intra- and inter-session variability will be similar in cross-sectional area measurements of the paired geniohyoid muscles and the left and right ABD muscles respectively.
6. The fixed-stand method will be less variable than the hand-held transducer method in cross-sectional area measurements of the paired geniohyoid muscles and the left and right ABD muscles, respectively.

Chapter 3 Methodology

3.1 Participants

Twenty-four healthy participants over the age of 50 years (51-84 years,

average age 66.4, 11 males and 13 females) were studied. An older age group was targeted as they may image differently from younger individuals (Stone, 2005). Data of normal swallowing function in the older population would also provide reference data for future studies of swallowing impairment particularly impairment after experiencing a stroke. Only 5% of strokes occur in people under the age of 45 (Ministry of Health, 2002). Incidence rates of first-time stroke rise exponentially after the age of 50 years particularly in females with a plateau effect in males after the age of 80 years (Ministry of Health, 2002). Current research into stroke incidence rates in New Zealand based on information gathered in the Auckland region suggest the average age of having a stroke is around 75 years for New Zealand Europeans, 61 years for Maori, 65 years for Pacific peoples, and 66 years for Asian and other populations (Carter, Anderson, Hacket, Feigin, Barber, Broad et al., 2006).

Power calculations were inferred from research undertaken in the same lab as this current study using similar but not identical methods (paper under preparation). The previous ultrasound study investigated the effects on floor of mouth muscle size pre and post-training after undertaking a mouth opening exercise on 14 healthy individuals. Results suggested an effect size (0.694) with 0.80 power could be detected using 19 participants when measuring differences in geniohyoid muscle area before and after training. When measuring differences in the anterior belly of the digastric muscles pre and 4-weeks post training an effect size with 0.83 can be detected using 6 participants. To assure adequate statistical power, 24 participants were recruited for this current study.

Exclusion criteria included any individual that had experienced a stroke; any brain-related condition or illness that caused brain injury; and any swallowing

difficulties. Written informed consent was obtained from each participant prior to commencement of data collection. Ethical approval was obtained from the New Zealand Health and Disability Ethics Committees, Central Region.

3.2 Instrumentation

Images were acquired using an Acuson Antares 5.0 Premium edition (Siemens Medical Systems) ultrasound device in a 2D B-mode imaging function. A VF13-5 linear transducer was used to measure submental muscles and a CH6-2 curved transducer was used to measure hyoid displacement. Each participant used an individually fitted dental bite block attached to a custom designed stand during the stabilised transducer and head tasks (refer Figure 4). The stand allowed for height, depth, lateral and angular adjustments of the transducer and vertical and horizontal adjustment of the individually fitted bite-blocks (refer Figure 5).

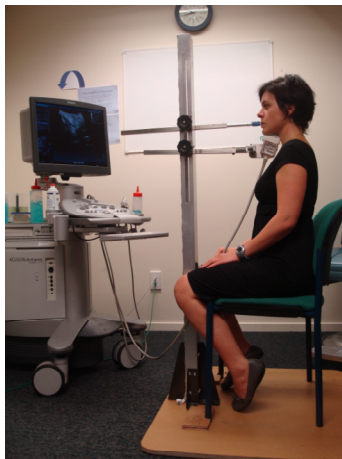


Figure 4. Custom designed stand

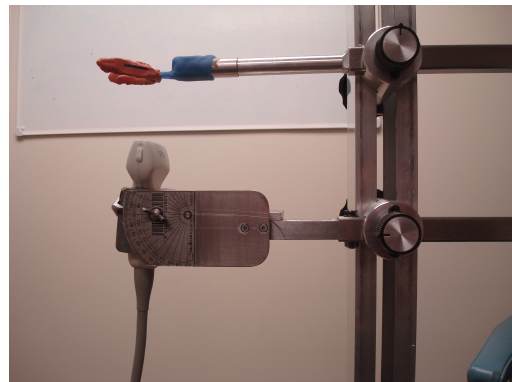


Figure 5. Close-up of custom designed stand

All setting parameters on the ultrasound device were kept constant within participant to control intra-individual variability. Setting parameters were adjusted

between participants for depth, frequency and contrast to gather “best” image. If required an acoustic stand-off pad was used to visualise the outer edges of the anterior belly of digastric muscles. Ultrasound conductive gel (Aquasonic) was applied to all coupling surfaces. All images were copied on to CDs and imported on to a DICOM viewer programme (Osirix) on an Apple iMac computer for data analysis.

3.3 Procedure

Each participant attended three sessions undertaken on three different days. Three sessions allowed for adequate repetition completed on different days in part to replicate what would occur in a normal clinical situation where patients would attend repeated sessions on different days. In the first session, the participants confirmed they had previously read the information sheet and had the opportunity to have any questions regarding the study answered. They then signed the consent form. A questionnaire was completed to ensure they were eligible to take part in the study.

An individual dental bite block was made to attach to the custom-designed stand (refer Figure 6). The dental bite block was fashioned in a two-part procedure. Before the session, a bite block form was created from a



Figure 6. Bite block components

light-curing hybrid composite resin (Plaque Photo[®]). In the first session, this hardened form was covered with a two-component Vinyl Polysiloxane Impression Material Putty (3M Espe Express[™] STD) and placed in the participant’s mouth. The participant was required to bite down on this product for approximately 60 seconds until the product set. This formed an individual dental

impression to control for head position during the tasks involving the stand. The bite-block was removed rinsed and trimmed with a scalpel to remove excess putty to allow for greater comfort while swallowing.

Participants were seated upright in a comfortable chair that was placed in position markers on the base-plate of the custom-designed stand. Four tasks, as described below, were undertaken in a counterbalanced order:

1 5-second video sweep of a dry swallow to image hyoid displacement using a hand held transducer

Ultrasound gel was liberally applied to a CH6-2 curved transducer. The examiner positioned the transducer under the participant's chin in a mid sagittal plane until the symphysis menti shadow was imaged on the left of the screen and hyoid shadow on the right. Ultrasound system parameters were adjusted until a "best" image was achieved. These were noted on a separate protocol sheet to keep all measurements consistent between recordings. The participant was asked to swallow and relax. During this time a 5-second video sweep was taken to capture the swallowing event. This was repeated four more times until five saliva swallows were captured. Between each swallowing trial the transducer was removed and the participant was given time to generate more saliva.

2 5-second video sweep of a dry swallow to image hyoid displacement using a stabilised transducer.

The participant's bite- block was connected to the upper arm of the

stand. When the participant was seated comfortably the arm was extended out towards the participant with horizontal and vertical adjustment made of the stand arm until it was positioned close to the participant's mouth. The participant was asked to carefully position their mouth around the bite block. A check was made to ensure the participant's teeth were in the right position.

Ultrasound conductive gel was liberally applied to a CH6-2 curved transducer, which was then attached to the lower arm of the custom designed stand in a mid sagittal plane. Vertical and horizontal adjustments of the bar and lateral and angle adjustments of the transducer holder were made until the muscles were adequately imaged as described above. All settings of the stand and ultrasound machine were noted on a separate protocol sheet to allow for exact and repeated settings in the next two sessions. The participant was asked to swallow and relax. During this time a 5-second video sweep was taken to capture the swallow. This was repeated four more times until five separate saliva-swallowing events were captured. Between each swallowing trial the participant remained positioned in the stand and bite-block and was given time to generate more saliva.

3 *Static imaging of submental muscles at rest using a hand-held transducer*

Ultrasound conductive gel was liberally applied to a VF13-5 linear transducer. The examiner held the transducer under the participant's chin approximately halfway between the symphysis menti and hyoid in a

coronal plane. Ultrasound system parameters were adjusted until a clear image of target muscles was achieved. These were noted on a separate protocol sheet to keep all measurements consistent between recordings. Five static images of the submental muscles at rest were taken with subtle adjustments in position made between trials to assure optimal image acquisition.

4 *Static imaging of submental muscles using a stabilised ultrasound transducer*

The participant's bite- block was connected to the upper arm of the stand. When the participant was seated comfortably the arm was extended out towards the participant with horizontal and vertical adjustment made of the stand arm until it was positioned close to the participant's mouth. The participant was asked to carefully position their mouth around the bite block. A check was made to ensure the participant's teeth were in the right position.

Ultrasound conductive gel was liberally applied to a VF13-5 linear transducer, which was then attached to the lower arm of the custom designed stand in a coronal plane. Vertical and horizontal adjustments of the bar and lateral and angle adjustments of the transducer holder were made until the muscles were adequately imaged as described above. All settings of the stand and ultrasound machine were noted on a separate protocol sheet to allow for exact and repeated settings in the next two sessions. Five static images of the submental muscles at rest were taken.

All four tasks were completed in the first session. All four tasks were repeated again in a further two sessions again using the same stand settings and ultrasound machine parameters as set in the first session. These tasks were presented in a randomised order in each session to avoid any possible order effects. All tasks were given a randomised code to enable blinding of the tasks and participants during data analysis. All measurements were performed by the same investigator to avoid inter-examiner variability.

3.4 Data extraction

All images were copied onto CD's and imported onto a DICOM viewer programme (Osirix) on an Apple iMac computer for data analysis. The length tool for 2D images in this programme was used on two selected frames from the 150 frames in the 5-second video sweep of hyoid movement during a swallowing event. The video was visually inspected to identify a frame of the hyoid at rest (usually at the start or end of the video when the participant was at rest) and at maximal contraction. The first frame was identified as having the greatest distance between the symphysis menti and hyoid bone shadows. The second frame was identified by following the movement of the hyoid shadow during the swallowing event until the shortest distance between the symphysis menti and hyoid bone shadows were found indicating the hyoid at maximal contraction. On each frame a line was drawn between two points of reference to calculate the length between shadows. The first reference point was at the posterior border of the symphysis menti shadow where it intersects with the inferior portion of the geniohyoid muscle, as displayed on the left side of the line in the images in Figure 7 and 8. The second reference point was at the anterior border of

the hyoid shadow where it intersects with the superior portion of the geniohyoid muscle, as displayed on the right side of the line in the images in Figure 7 and 8. Data analysis was based on percentage change in hyoid proximity between rest and maximal hyoid excursion. This was calculated by subtracting the length of hyoid at maximal contraction from hyoid at rest, multiplying this by 100 and then dividing it from measurement of hyoid at rest.

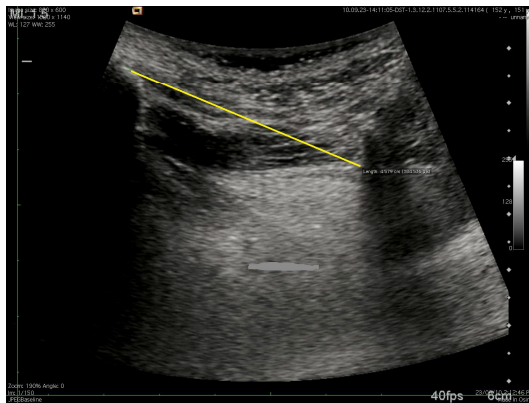


Figure 7. Hyoid at rest, the mandible shadow is on the left and the hyoid shadow is on the right of the image.

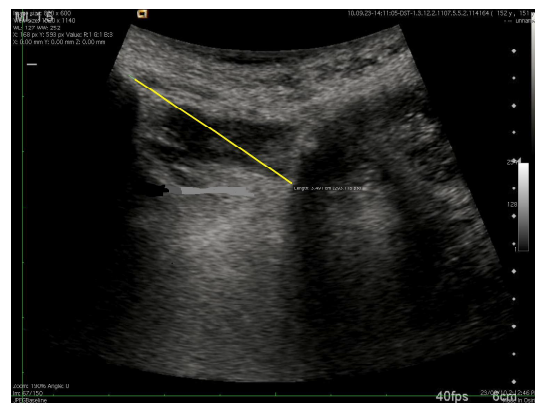


Figure 8. Hyoid at maximal contraction

The closed polygon trace tool for 2D images in this programme was used to calculate the circumference in cm^2 of the paired geniohyoid muscles and the left and right ABD muscles. The electronic trace was manually drawn around the muscle perimeters and automatically calculated once the polygon was complete. The left and right of the ABD muscle were traced separately while the paired geniohyoid muscles were traced as one muscle as delineation of the muscles was not possible (refer Figure 9).

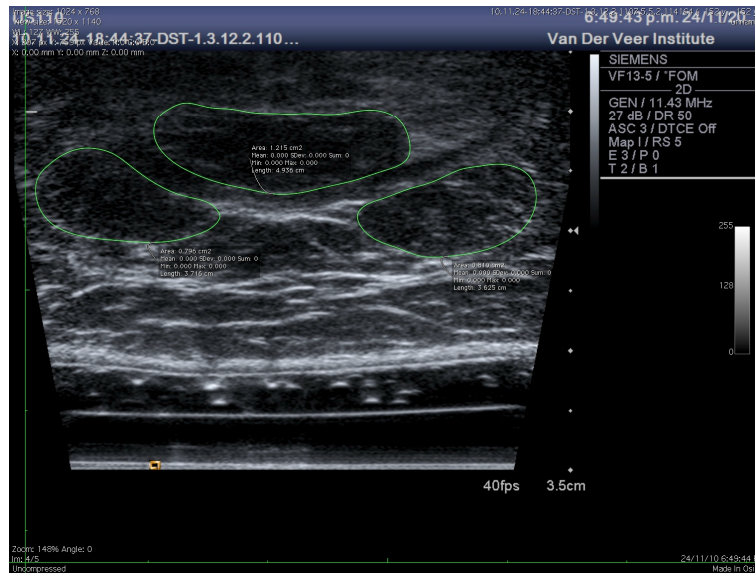


Figure 9. Cross sectional area measurements of the floor of mouth muscles.

3.5 Statistical analysis

To analyse the descriptive statistics, the R statistical analysis environment (R Development Core Team, 2010) was used. Individual values from each participant for each trial in each session were plotted for the measure of percent change in hyoid displacement and for each of the floor of mouth muscles measurements.

In standard repeated measures analysis of variance problems can occur when there is not compound symmetry (sphericity). When violations occur in the assumption of sphericity adjustments are needed. While there is not universal agreement on the success of these adjustments they are usually performed using adjustments proposed by Greenhouse and Geisser and by Huynh and Feldt (Howell, 2010). Problems also occur when there is incomplete data. If a participant has missing data e.g. he misses a session or as was the case of this current study his data is unable to be analysed, then his data needs to be eliminated from the analysis. Another type of analysis can be performed which does not require an assumption of sphericity or complete data. This alternative approach is often referred to as mixed models,

multilevel modelling, or hierarchical modelling (Howell, 2010).

As the data set in this current study contained missing values, analyses of the repeated measures design were performed using a linear mixed effect model. This analysis uses a restricted maximum likelihood (REML) approach to make parameter estimations rather than the typical least squares approach, which requires complete data (Howell, 2010).

In the R statistical analysis environment (R Development Core Team, 2010) the nlme package (Pinheiro & Bates, 2000) was used to estimate the effects of session, trial, and method on the measures of percent change in hyoid displacement and 2D cross-sectional area measurements of the paired geniohyoid, left and right ABD muscles. Variance between participants, sessions, trials, and methods were also modelled. Confidence intervals were calculated to indicate the degree of uncertainty in the estimation of parameters. To compare the different variances by method for the within-group error the lme variance function was used to model heteroscedasticity by using a weights argument. This produces an estimated ratio of the different variances (Pinheiro & Bates, 2000). Heteroscedasticity occurs if the random variables have different (unequal) variance. When a sequence of random variables has constant variables it is known as homoscedastic in statistical terms.

Chapter 4 Results

4.1 Hyoid displacement

Out of a possible 720 measures of hyoid displacement, 45 measures (6.25%) were not analysed. This included five measures using the stand method (0.69%) and

one measure using the hand-held method (0.14%) that were not recorded or the swallowing event was not fully captured in the 5-second video sweep. Other measures could not be analysed because the images were not clear enough to interpret accurately and included 37 (5.14%) of stand measurements and two (0.28%) of the hand-held measurements.

All measures of hyoid displacement measured in percent change are displayed Figure 10. It displays the five trials within the session for each individual across the length of the graph giving an indication of within session variability. Session one measures are displayed at the top of the graph, session two in the middle and session three at the bottom of the graph. The stand condition is displayed in blue, while the hand-held condition is displayed in red.

Results using the linear mixed effects model to estimate mean values of order effects with 95% confidence intervals are shown in Table 1. The intercept corresponds to the estimated mean value of percent change in the hand-held method in session one, trial one. There were no significant effects of session and trial with order effects that were 0.5% different from the baseline measure with an estimated maximum change that was no larger than 4.4% for session and 1.5% for trial. There was a significant effect of method, with a systematic decrease in the stand measures that were estimated as being 9.3% less than the estimated baseline hand-held condition method. The maximum possible change in the stand condition was estimated as 16% different from baseline hand-held condition measure.

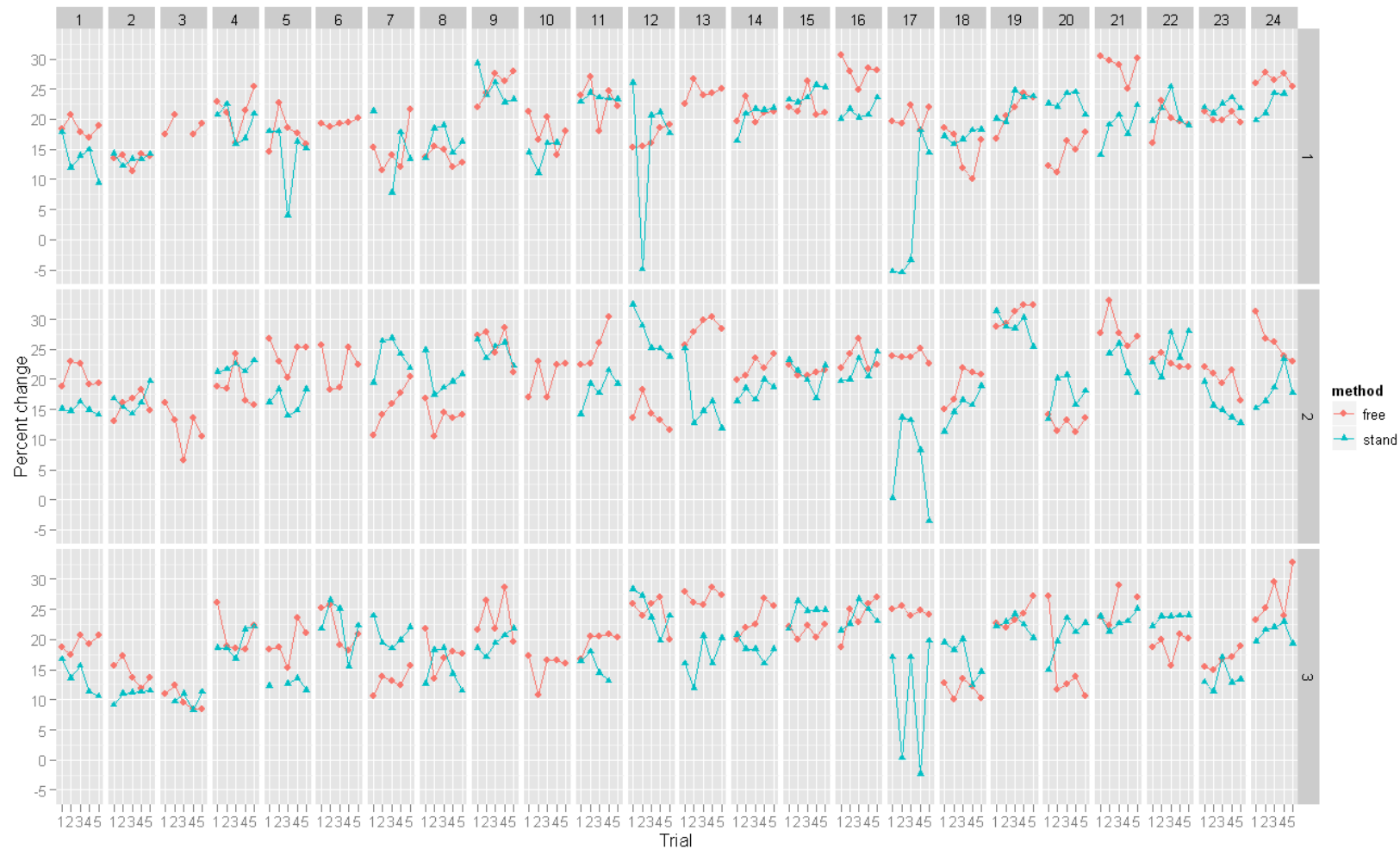


Figure 10: Individual values of percent change in measures of hyoid displacement for each participant in each trial in each session. All measures of hyoid displacement measured in percent change. The five trials within the session for each individual are displayed across the length of the graph giving an indication of within session variability. The different sessions are displayed vertically with session one measures displayed at the top of the graph, session two in the middle and session three at the bottom of the graph. The fixed-stand condition is displayed as blue triangles, while the hand-held condition is displayed as red diamonds.

Table 1. Linear mixed effects model of estimated means with 95% confidence intervals in measures of percent change in hyoid displacement.

	Value (% change)	95% CI	DF	<i>p</i>- value
(Intercept)	20.4	[18.7 to 22.0]	537	0.000
Method stand	-1.9	[-3.2 to -0.6]	64	0.004
Session	-0.1	[-0.9 to 0.7]	47	0.80
Trial	0.1	[-0.1 to 0.3]	537	0.26

The estimates of variability expressed as standard deviations in the measures of percent change were 2.3% between participants, 0.13% between trials, 2.3% between sessions, and 3.1% between methods indicating greater variability across sessions than within sessions. The estimated ratio of the variances between the two methods found 43% greater variability when using the stand method compared to the hand-held method.

4.2 2D area of submental muscles

Out of a possible 720 measures of the paired geniohyoid muscles, 165 measures (23%) could not be analysed. This included one image (0.14%) using the stand method that was not captured fully and therefore was counted as missing data. Eighty-one stand (11%) and 83 hand-held (11.5%) measures were not analysed, as images were not clear enough to delineate borders. Out of a possible 1440 measures of the left and right ABD muscles, 32 measures (2%) could not be analysed. This included the one image (2 measures, 0.14%) using the stand method that was not fully captured and 20 stand measures (1.4%) and 10 hand-held (0.7%) measures that were not clear enough to delineate borders.

Figure 11 displays the individual values for all 24 participants for each of the five trials in each of the three sessions using the stand and hand-held methods for the

measures of the paired geniohyoid muscles. Figure 12 displays individual values from the left ABD muscles and Figure 13 displays individual values from the right ABD muscles.

Results using the linear mixed effects model to estimate mean values of order effects with 95% confidence intervals are recorded in Table 2. The intercept corresponds to the estimated mean value of CSA muscle measures in cm^2 in the hand-held method in session one, trial one.

In the paired geniohyoid muscle measures there were no significant effects of session, trial or method. The order effects of session were <3% different from the baseline measure with the estimated maximum change no larger than 13%. The order effects of trial were <0.4% different from baseline with the estimated maximum change no larger than 0.7%. The order effects of method were 5.3% greater than the baseline measure with estimated maximum change no larger than 21%.

In the ABD muscles there were significant effects of trial in the hand-held measures with small systematic increases that were <0.5% different from baseline with the estimated maximum change no larger than 0.8%. There were no significant effects of session and method. The order effects of session were <2% different from baseline with the estimated maximum change no larger than 5.5%. The order effects of method were <4.5% different from baseline with the estimated maximum change no larger than 10%.

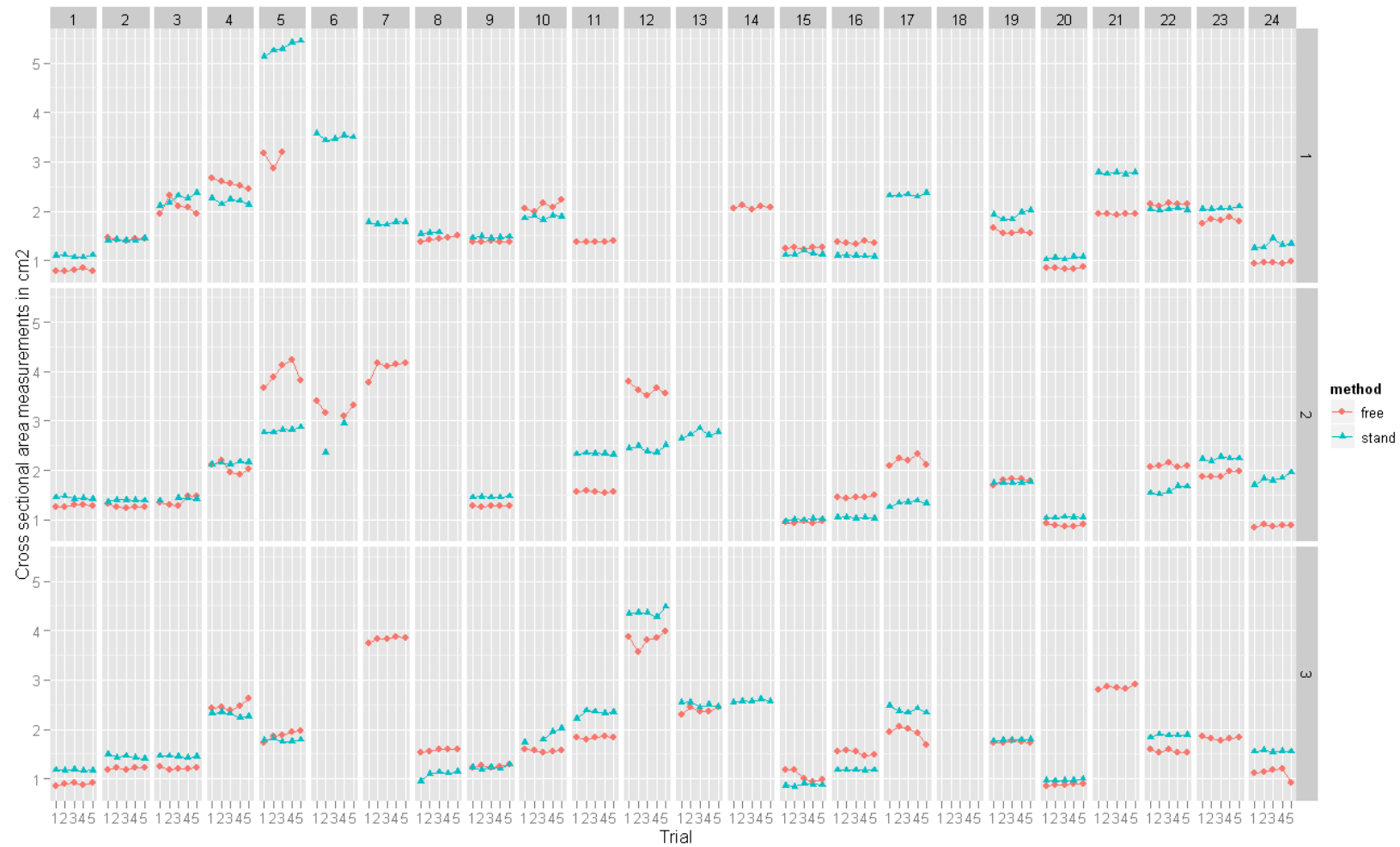


Figure 11: Individual values of cross sectional area measurements in cm² of the paired geniohyoid muscles for each participant in each trial in each session. The five trials within the session for each individual are displayed horizontally across the length of the graph giving an indication of within session variability. The different sessions are displayed vertically with session one measures displayed at the top of the graph, session two in the middle and session three at the bottom of the graph. The fixed-stand condition is displayed as blue triangles, while the hand-held condition is displayed as red diamonds.

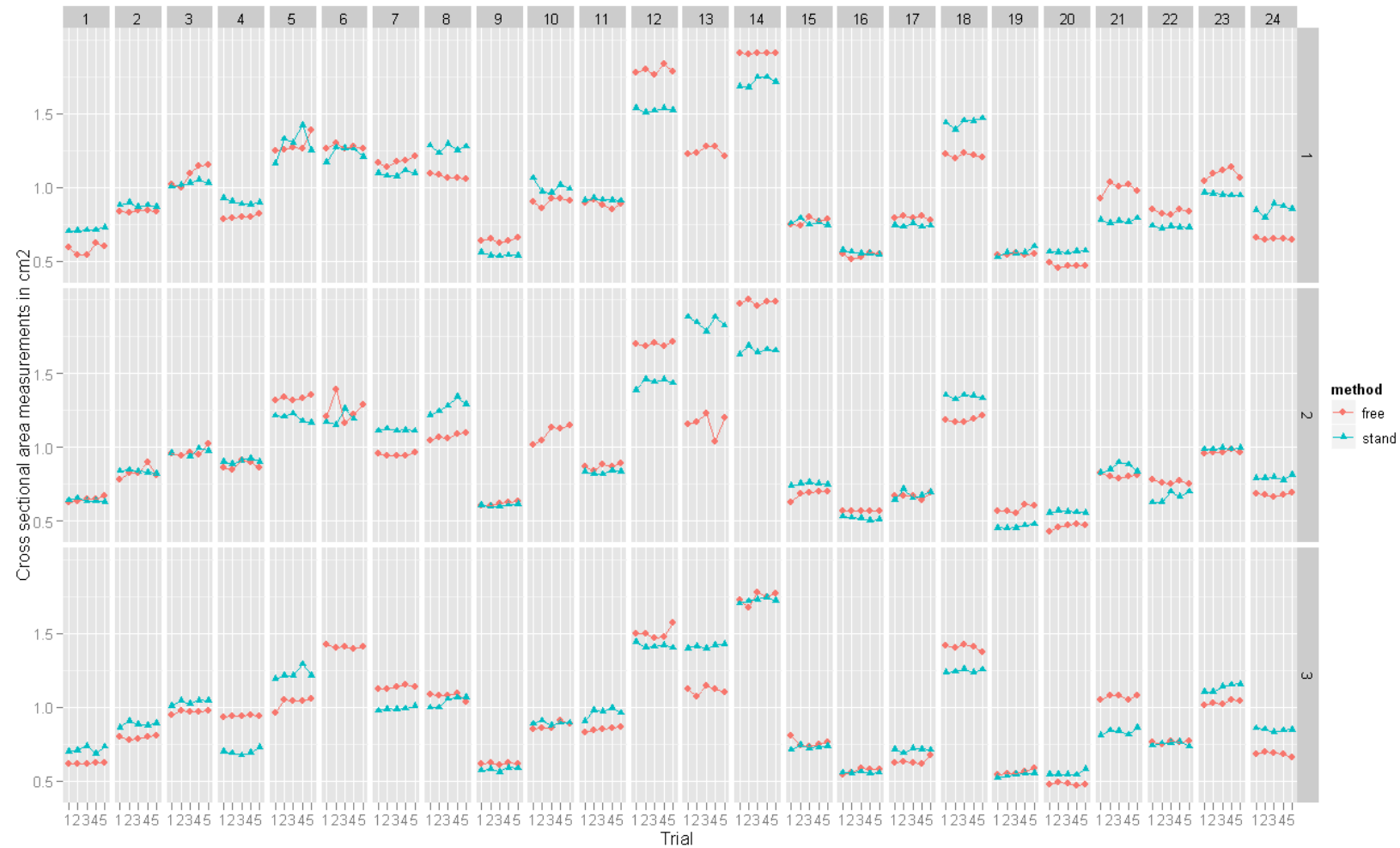


Figure 12: Individual values of cross sectional area measurements in cm^2 of the left anterior belly of digastric muscle for each participant in each trial in each session. The five trials within the session for each individual are displayed horizontally across the length of the graph giving an indication of within session variability. The different sessions are displayed vertically with session one measures displayed at the top of the graph, session two in the middle and session three at the bottom of the graph. The fixed-stand condition is displayed as blue triangles, while the hand-held condition is displayed as red diamonds.

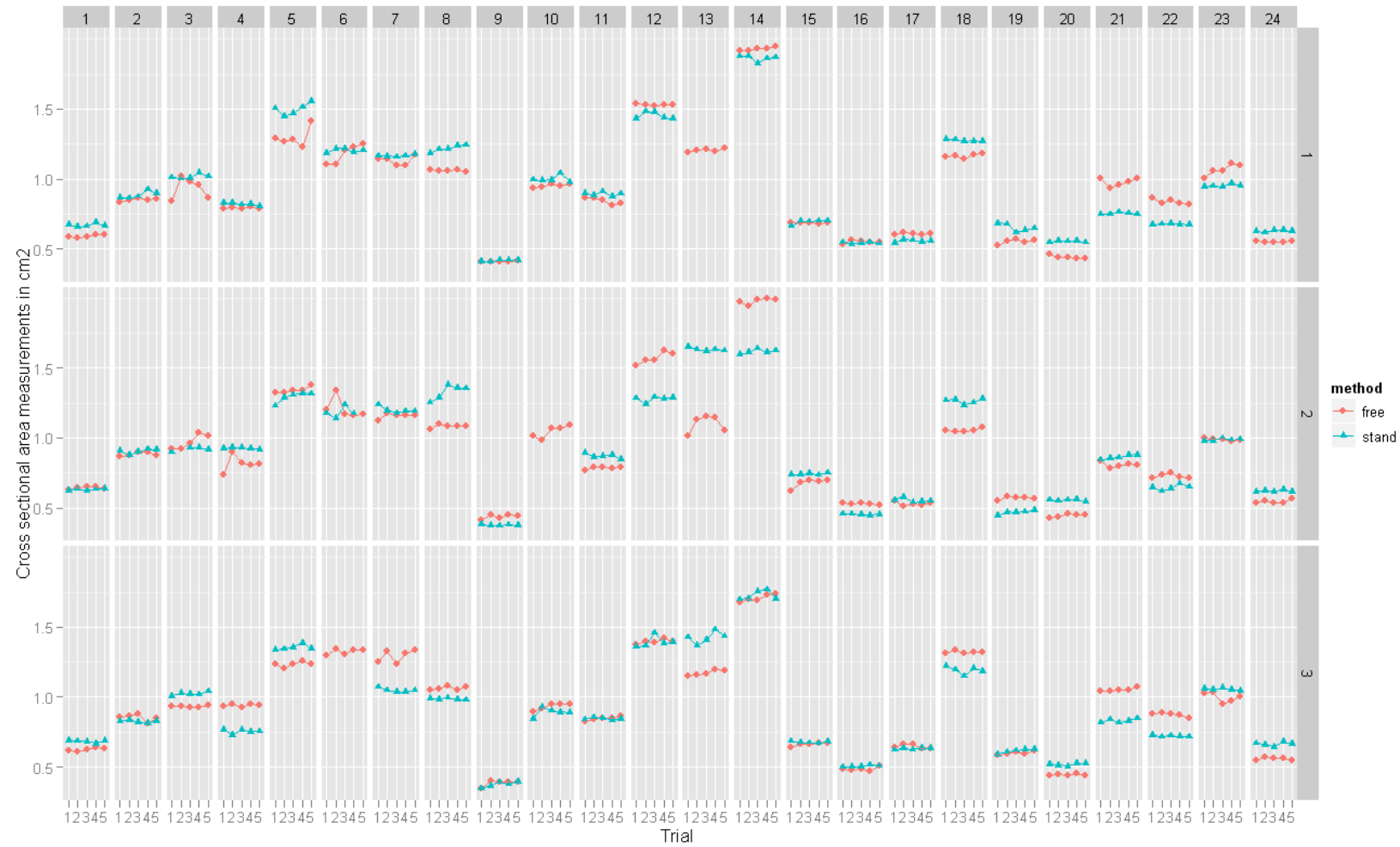


Figure 13: Individual values of cross sectional area measurements in cm² of the right anterior belly of digastric muscle for each participant in each trial in each session. The five trials within the session for each individual are displayed horizontally across the length of the graph giving an indication of within session variability. The different sessions are displayed vertically with session one measures displayed at the top of the graph, session two in the middle and session three at the bottom of the graph. The fixed-stand condition is displayed as blue triangles, while the hand-held condition is displayed as red diamonds.

Table 2. Linear mixed effects model of estimated means with 95% confidence intervals in CSA measurement in cm² of the submental muscles.

Muscle		Value (cm ²)	95% CI	DF	p-value
Geniohyoid	(Intercept)	1.9	[1.6 to 2.3]	440	0.0000
	Method stand	0.1	[-0.1 to 0.4]	49	0.35
	Session	0.001	[-0.16 to 0.16]	38	0.99
	Trial	0.006	[-0.002 to 0.013]	440	0.13
	Method stand: Session	-0.06	[-0.24 to 0.12]	49	0.52
	Method stand: Trial	0.007	[-0.001 to 0.014]	440	0.09
Left Anterior Belly of Digastric	(Intercept)	0.91	[0.77 to 1.05]	561	0.000
	Method stand	0.04	[-0.01 to 0.09]	23	0.16
	Session	0.004	[-0.02 to 0.02]	91	0.69
	Trial	0.005	[0.002 to 0.007]	561	0.0001
	Method stand: Session	-0.02	[-0.05 to 0.01]	91	0.10
	Method stand: Trial	-0.002	[0.004 to 0.000]	561	0.10
Right Anterior Belly of Digastric	(Intercept)	0.96	[0.82 to 1.10]	561	0.000
	Method stand	0.02	[-0.05 to 0.08]	23	0.62
	Session	-0.02	[-0.04 to 0.01]	91	0.15
	Trial	0.005	[0.003 to 0.007]	561	0.0000
	Method stand: Session	0.004	[-0.04 to 0.03]	91	0.83
	Method stand: Trial	-0.002	[-0.004 to 0.001]	561	0.24

The estimates of variability expressed as standard deviations in measures of muscle size in cm² are recorded in Table 3 for each of the submental muscles. There was greater variability across sessions than within sessions in all measures. The estimated ratio of variances between the two methods found 29% less variance in the paired geniohyoid muscles, 33% less variance in the left and 11% less variance in the right ABD muscles when using the stand method compared to the hand-held method.

Table 3. Estimated variability in measures of submental muscle size expressed as standard deviations in cm²

Muscle	Parameter	SD in cm²
Geniohyoid	Between participants	0.69
	Between trials	0.01
	Between sessions	0.32
	Between methods	0.38
Left anterior belly of digastric	Between participant	0.34
	Between trial	0.003
	Between session	0.07
	Between method	0.06
Right anterior belly of digastric	Between participant	0.33
	Between trial	0.001
	Between session	0.08
	Between method	0.08

Chapter 5 Discussion

This study evaluated the variability in ultrasound measures of hyoid displacement and submental muscle size within and between sessions using two methods of data acquisition in normal participants. This study provides important information for researchers who hope to use repeated measures from ultrasound imaging as an outcome measure in rehabilitation research.

5.1 Hyoid displacement

As hypothesised, no significant effects were found within and between sessions. Inferential results suggest the percent change in measures of hyoid displacement change less than 0.5% due to order effects with a maximal change that is no greater than 4.5% across sessions and 1.5% across trials. However any clinically relevant differences might have been difficult to detect because of the wide variability in individual measures (as displayed in Figure 11). Wide intra-individual variability

during swallowing as indicated in this current study has also been documented in ultrasound studies of tongue movement (Cheng et al., 2002; Galen & Brinkmann, 2010; Soder & Miller, 2002). Heterogeneity during swallowing suggests researchers should use caution when using hyoid displacement during ultrasound imaging as an outcome measure of rehabilitative techniques. Researchers also need to consider the greater variability found across session than within session when using repeated measures as an outcome measure.

The findings also suggest that stabilising the transducer and participant in a stand during a swallowing event may not be as effective as using a manually held transducer. This finding was different than hypothesised. Measures of hyoid displacement were significantly smaller when using the stabilised transducer method. There was also greater variation in the stabilised transducer method when compared to the hand-held method of stabilisation.

The stand may have had an effect on swallowing in a number of the participants. Whalen et al. (2005) suggested that fixed participants and transducers could impede jaw movement and that certain people may find it difficult to undergo immobilisation. Peng et al. (1996) suggested their CST method of stabilisation provided more standardised and objective measures than hand-held techniques but their results indicated that the duration and range of tongue movement during swallowing was significantly lower when using the CST compared to the hand-held technique. Soder and Miller (2002) rejected using the CST method of transducer stabilisation, as it appeared to impede swallowing and participants in a pilot study found it uncomfortable. While no participants complained of discomfort when using the custom designed stand in the current study some participants did report finding it

harder to swallow while using the stand. Having a bite-block in the mouth may have also made it harder to swallow because it may have felt unnatural. Five measures made during the stand condition were not analysed because the swallowing event was not fully captured in the 5-second sweep.

Some participants had negative values of percent change while using the stand. This occurred when there was superior movement but not anterior movement of the hyoid during the swallowing event. While the participants reported they had executed a swallow it was possible that they had not. Calculation of percent change in hyoid movement involved measurement from two reference points (i.e. the intersection of the floor of muscles with the mandible shadow and the intersection of the floor of mouth muscles with the hyoid shadow). In measures using the stabilised transducer, the jaw became immobile so that one reference point remained constant. However, when using the hand-held method both reference points had the capacity to move from original position. While attempts were made to keep the transducer as steady as possible during the hand-held measures, there is always the opportunity for movement to occur. Stable hand-held transducer positioning was particularly difficult to maintain during some measures of hyoid displacement. This occurred during imaging of male participants that had a prominent thyroid notch. During the swallowing act the superior movement of the thyroid caused the transducer to be pushed out of position.

The reference markers as described above were not always easy to establish. Using two reference points that both had the capacity to move and with no fixed reference system during analysis may have contributed to measurement error and variability. Calculating hyoid movement using a one-dimensional distance measure on

two-dimensional images may not be an accurate way to measure displacement.

A phenomenon described as “blacking out” occurred when using the stand on some thinner individuals. During the swallow particularly at the peak of hyolaryngeal excursion contact was lost between the transducer and the skin of the participant. This resulted in a blacking out of the image on the ultrasound screen. The blacking out of images accounted for most of the images that could not be analysed when using the stand for measures of hyoid displacement.

5.1.1 Limitations

Image quality was based on the parameters the investigator set as “best” image constrained by the capabilities of the current ultrasound device. These images were all acquired by same investigator to diminish inter-examiner variability. Data analysis of images captured was also performed by one investigator using manual methods of data extraction based on visual judgement. Therefore all measurements involved a subjective element and possible subjective error by the investigator during acquisition and analysis. Further research is required to develop techniques that would reduce subjective error. Further research would also be required to investigate interexaminer reliability during acquisition and to examine intra-and inter-rater reliability during data analysis.

The wide variability in individual measures indicates further research is required before ultrasound measurement of hyoid displacement could be used as an outcome measurement of rehabilitative effects. Future researchers may need to decide whether to include or exclude participants that display large variation or do not image well into their research design.

5.2 Submental muscle size

Individual measures of the paired geniohyoid muscle displayed wide variation in some individuals more than others (as displayed in Figure 12). The estimated 95% confidence intervals were also quite large. The possible maximum change was 13% in sessions using the stand method and 21% when using the stand method compared to the baseline measure of the hand-held method in session one, trial one. As hypothesized there were no significant effects within and across sessions and between different methods however the wide variation in measures may have made it difficult to detect any possible significance. Different to what was hypothesized the variation in estimated standard deviations was considerably larger across sessions than within sessions. Researchers need to consider the large variability in measures particularly the variability found across sessions when using repeated measures of the paired geniohyoid muscle as an outcome measure.

Measures of the left and right ABD muscles displayed less variation in individual measures particularly in some participants more than others (as displayed in Figures 13 and 14). As hypothesised, no significant order effect of session or method was found. However, a significant effect of trial was found in the hand-held measures of both the left and right ABD muscles although the effect was minor. The change was 0.5% from the estimated baseline value with a possible maximum change that was no larger than 0.8%. The consistency of measures suggests ultrasound measurement of the ABD muscles could be a reliable measure of treatment effects. However researchers need to be aware of the greater variance across session than within session.

As hypothesised the stabilised transducer and participant in a stand method

provided less variance in 2D cross-sectional area measurements in all of the muscles measured compared to the hand-held transducer method. When using the custom-designed stand, site measurements were recorded in the first session and repeated in the further two sessions. However, when using the hand-held method the site measurement was not recorded. Positioning of the transducer was based on a visual estimation of placement that was approximately halfway between the symphysis menti and the hyoid bone. If clinicians and researches intend to use ultrasound imaging as an outcome measure in measures of submental muscle size it will be important to establish a consistent site of measurement. When imaging the tongue in a coronal plane, Chi-Fishman et al., (1998) positioned the transducer 2.7 to 3.2cm (approximately a third of the jaw length) back from the symphysis menti using callipers to measure the distance on the participant's right side. Callipers could be used to establish a regular position that could be marked with a washable skin marker to enable consistency within session. This measure could be recorded on a protocol sheet to enable consistency across sessions.

Difficulties can arise during hand-held transducer placement because there is no anatomic structure to stabilise the transducer (Peng et al. 1996). A possible cause of the significant difference in trials using the hand-held method for measurement of digastric muscles may have occurred through a difference in transducer pressure. A possible fatigue effect may have occurred while the examiner was trying to hold the transducer steady under the participant's chin.

A possible cause of the larger variation across session than within session may be due to the blinding used during analysis of results. The five trials within each task were analysed together because it was not possible to separate them. However, during

acquisition the tasks were assigned a random code so that during analysis the examiner was blinded to method and participant used. While it is essential to include blinding during research to avoid bias, in a clinical situation it would be important to be able to review and compare images taken before and after treatment. This would allow for correct and consistent identification of the borders of the tissues.

The edges of the paired geniohyoid muscles were particularly difficult to image. Unclear delineation of their borders meant that some measures might have included part of the mylohyoid and genioglossus muscles into the cross-sectional area calculation. Over 22% of the paired geniohyoid muscles measurements could not be analysed because it was too difficult to delineate the borders. While imaging of the digastric muscles appeared easier to achieve, anecdotally at times these images were also difficult to analyse. Emshoff et al. (1999) suggested visualising the digastric muscles in real time to help identify the outer contours of the muscles and to not confuse them with the surrounding hypoechogenic fat.

The clarity of the ultrasound images is an important factor to consider in regards to the study findings. More consistent measurements of muscle size are achieved when the tissue interfaces are well defined (Ishida et al., 1992). In some participants the 13-5 MHz linear transducer used in the current study was not large enough to capture the lateral borders of the ABD muscles. The transducer had to be set in a sector array rather than a linear array in a number of participants. This meant the beam width widened the further it moved away from the transducer possibly causing a degradation of the image. An acoustic standoff pad was also used with some participants to enable imaging of the lateral borders of the ABD muscles. Imaging of the deeper paired geniohyoid muscles may have been affected by selection of the

sector array and use of the acoustic standoff pad. Resolution would have deteriorated the deeper the acoustic energy had to travel and the wider the beam became.

The tissue composition and anatomy of the participants require further comment. Generally thinner participants image better than larger participants, younger participants image better than older participants, and women image better than men (Stone, 2005). While the gender and age effects of the participants were not analysed in this current study participants were recruited from the over 50-year-old population. Having an older population age group may have had an effect on image quality. A possible cause may be due to older people having proportionately more fatty tissue in and around their muscle tissue as fat tends to scatter sound (Stone, 2005). Participants with greater submental fat in this current study were generally more difficult to image especially in measures of muscle size. Future researchers may need to consider whether to include or exclude participants that do not image well in to their research design.

5.2.1 Limitations

The limitations in ultrasound measurement of submental muscles are similar to the limitations described in ultrasound measurement of hyoid displacement. The imaging parameters of the ultrasound machine were set to “best image” as decided by the examiner within the confines of the equipment used and the participant being examined. Instrument settings were kept constant within participant but not between participants. If the aim of this study was to achieve normative data then the settings would need to remain constant between participants. As such this current study provides guidance to future studies involving ultrasound imaging of the submental

muscles and provides some indication of the variability that needs to be considered before using it as an outcome measure of rehabilitative techniques. Further research is required to investigate the reliability of different examiners in obtaining ultrasound images of submental muscle size and to examine intra-and inter-rater reliability during data analysis.

Conclusion

The results from this study provide guidance to researchers who use repeated measures from ultrasound imaging as an outcome measure in swallowing research. In terms of ultrasound measurement of hyoid displacement there appears to be wide intra-individual variability during swallowing events. Further research may be required before clinicians could use it in a clinical situation to measure treatment effects in individual patients. If stabilisation is used then care should be taken that the stabilisation is not restricting the participant's ability to swallow.

The large variability within and across participants in measures of geniohyoid muscle size may also require further investigation. When the variation described in this current study is considered then ultrasound imaging of the cross-sectional area measurements of ABD muscles could be a valuable outcome measure in treatment studies. Stabilisation will ensure more consistent measures by providing a consistent site of measurement.

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Appendices

Appendix 1: Protocol Sheet

Appendix 2: Advertisement for participants

Appendix 3: Consent Form

Appendix 4: Questionnaire

Appendix 5: Information sheet

Appendix 1: Protocol Sheet

Participant Data Sheet
Reliability Measures

Participant: _____

Session: _____

Date of Birth: _____

Code	Task		Measurements LBD = left belly of digastric RBD = right belly of digastric GH = Geniohyoid HAR = hyoid at rest HAMC = hyoid at maximal contraction
US		1	
		2	
		3	
		4	
		5	
US			
		1	
		2	
		3	
		4	
		5	
US			
		1	
		2	
		3	
		4	
		5	
US			
		1	
		2	
		3	
		4	
		5	

Participant Data Sheet

Ultrasound and Stand Settings

Participant: _____

Date of Birth: _____

Stand Settings	HYOID	FOM	
Bite block bar Horizontal/Depth		Bite block bar Horizontal/Depth	
Bite block bar Vertical/height		Bite block bar Vertical/height	
HYOID transducer Horizontal/Depth		FOM transducer Horizontal/Depth	
HYOID transducer Vertical/Height		FOM transducer Vertical/height	
Protractor degree		Protractor degree	
Transducer lateral measure		Transducer lateral measure	

Ultrasound Settings

	HYOID	FOM
Transducer	CH6-2	VF13-5
Brightness %		
2D (dB)		
Frequency (MHz)		
Focus points		
Focus location		
Gain DR (dB)		
R/S		
Map		
Tint		
Sie Clear		
Dynamic TCE	off/low/medium/high	off/low/medium/high
Edge (page 2)	1 / 2 / 3	1 / 2 / 3
Shape	Rectangle / Wedge	Rectangle / Wedge
Depth (cm)		
Width of image (Priority tool)		

Appendix 2: Advertisement for participants



RESEARCH PARTICIPANTS WANTED

We are looking for healthy participants aged 18 years or older to investigate the effect of exercise on swallowing and the reliability of measuring these effects.



Picture 1



Picture 2

This study will use ultrasound to evaluate how two different rehabilitative swallowing techniques affect the movement of the muscles and bones under the chin during swallowing. In addition, we will evaluate the reliability of a researcher making repeated measurements when using a free-held ultrasound transducer (as shown in picture 1) and using the transducer when it is fixed in a stand (as shown in picture 2).

A questionnaire will be carried out prior to your involvement to ensure your suitability for the study and to ensure there is no risk associated with your participation in this study.

You will be asked to perform a number of different swallows during three sessions lasting a total of approximately three hours. The first session will be around one and half hours with two subsequent sessions of around 45 minutes each. You will be asked to perform the same tasks in each session.

If you do agree to take part in this study, you are free to withdraw at any time, without having to give a reason.

If you are interested in participating, please contact:

Corina Winkelman

Van der Veer Institute for Parkinson's and Brain Research, 66 Stewart St., Christchurch

Ph: 03 378 6068 or 021 027 18815

or email: cjw177@uclive.ac.nz

Appendix 3: Consent form



CONSENT FORM

The effect of exercise on swallowing and reliability of measurement

English	I wish to have an interpreter	Yes	No
M•ori	E hiahia ana ahau ki tetahi kaiwhaka M•ori/kaiwhaka pakeha korero	Ae	Kao
Cook Island M•ori	Ka inangaro au i tetai tangata uri reo	Ae	Kare
Fijian	Au gadreva me dua e vakadewa vosa vei au	Io	Sega
Niuean	Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu	E	Nakai
S•moan	Ou te mana'o ia i ai se fa'amatala upu	loe	Leai
Tokelaun	Ko au e fofou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika	loe	Leai
Tongan	Oku ou fiema'u ha fakatonulea	Io	Ikai

I, _____, have read and I understand the Information Sheet dated _____ for volunteers taking part in the study containing two parts. The first part of the study will compare two swallowing manoeuvres with normal swallows to measure their effect on swallowing dynamics. The second part of the study will evaluate two methods of ultrasound transducer placement for consistency of measurement across sessions. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.

I have had this project explained to me by _____

I have had the opportunity to use whanau support or a friend to help me ask questions and understand the study.

I understand that taking part in this study is voluntary (my choice), and that I may withdraw from the study at any time, and, if applicable, this will in no way affect my academic progress. I understand that if I choose to withdraw from the study, I may also withdraw all information that I have provided.

I understand that the information obtained from this research may be published. However, I understand that my participation in this study is confidential and that no material which could identify me will be used in any reports on this study.

I understand that the investigation will be stopped if it should appear harmful to me and I know whom to contact if I have any side effects to the study or have any questions about the study.

I understand there are potential risks of participation in the study as explained to me by the researcher. I have filled out the questionnaire, and I feel confident that none of the risk factor outlined in the questionnaire apply to me.

I consent to the use of my data for future related studies, which have been given ethical approval from a Health and Disability Ethics Committee.

I have had time to consider whether to take part.

I wish to receive a copy of the results.

YES / NO

* Please note that a significant delay may occur between data collection and publication of the results

I, _____, (*full name*) hereby consent to take part in this study

Date _____

Signature of participant _____

Signature of researcher _____

Name of researcher _____

Name of primary researcher and contact phone numbers:

Name: Corina Winkelman

Work: 03-3786068

Home: 021-02718815

(Note: A copy of the consent form to be retained by participant)

Appendix 4: Questionnaire



QUESTIONNAIRE

The effect of exercise on swallowing and reliability of measurement

Identifying number: _____

Age: _____

Which ethnic group do you belong to:

☐ New Zealand European

☐ Samoan

☐ Tongan

☐ Chinese

☐ Other _____

☐ New Zealand Maori

☐ Cook Island Maori

☐ Niuean

☐ Indian

Please complete the following questionnaire by ticking the box that is most applicable to you.

All Participants - do you suffer from the effects of any of the following medical problems?

- ☐ Stroke
- ☐ Swallowing difficulties
- ☐ Head and/or neck injury
- ☐ Head/ and/or neck surgery
- ☐ Neurological disorders (eg. Multiple Sclerosis etc.)
- ☐ Gastroesophageal Reflux Disease

Are you currently taking any medications that may affect your swallowing?
(for example: muscle relaxants, anti-anxiety medications, anti-depressants, anti-histamines)

Yes / No (Please circle one) Name of Drug: _____

If yes, please describe any difficulties you may be experiencing

Do you have any other medical problems which you feel may impact on your ability to participate?

Yes / No (Please circle one)

If yes, please describe



INFORMATION SHEET

The effect of exercise on swallowing and reliability of measurement

Primary Researcher:

Corina Winkelman, BSLT
Masters candidate, Department of Communication Disorders
University of Canterbury
Van der Veer Institute for Parkinson's and Brain Research
66 Stewart St., Christchurch NZ
(03) 378 6068

Principal Investigator:

Maggie-Lee Huckabee, PhD
Senior lecturer, Department of Communication Disorders
University of Canterbury
Van der Veer Institute for Parkinson's and Brain Research
66 Stewart St., Christchurch NZ
(03) 378 6070

Co-Investigator:

Michael Robb, PhD
Professor and Head of Department
Department of Communication Disorders
University of Canterbury
Private Bag 4800
Christchurch NZ
(03) 364 2987 ext 6341

Introduction and aims of the project:

You are invited to participate in a research project that will contain two separate components. First the study will evaluate two swallowing exercises that are commonly prescribed for patients with swallowing impairment. This study will measure how these exercises influence movement of a small bone in the neck that is critical for swallowing efficiency (the hyoid bone).

In addition, the study will explore two different methods of measuring swallowing using ultrasound and the consistency of a researcher in making these measures. The first technique involves the researcher holding the ultrasound measurement device (transducer) under your chin. The second measure involves stabilising the transducer and your mouth in a support stand to limit variability of measurement.

Interest in participating should be expressed within 2 weeks of the information being provided. You have the right not to participate in the study or subsequently withdraw from this study at any time.

The aim of this project is twofold: First, to provide important information on two rehabilitative techniques that are used in the treatment of swallowing disorders. Secondly, to provide important information regarding a method of measuring the effects of rehabilitative techniques on swallowing disorders. Swallowing disorders can occur as a result of stroke, or other neurological conditions such as Parkinson's or Huntington's disease. By refining our knowledge of particular rehabilitative swallowing techniques we can improve treatment approaches. By refining the way we use this measuring tool, we can provide optimal measuring practices to use in research of swallowing disorders.

Participant selection:

Your participation in this study is due to your reply to advertisements requesting research participants. Upon your consent, you will complete a questionnaire that will determine your suitability for the study. The study will include 24 participants over the age of 18 years. In total this study will require approximately 3 hours of your time completed in three sessions.

Exclusion criteria:

You may not be eligible to participate in this study if you have or ever have had any of the following conditions:

- stroke
- any brain-related condition or any illness that caused brain injury
- any swallowing difficulties

Completing a questionnaire before beginning the study will ensure that inclusion criteria are met and possible risk factors for participating are identified.

The research procedure:

The study involves three sessions at the Van der Veer Institute for Parkinson's and Brain Research. The first session will involve approximately one and half hours with two subsequent sessions of around 45 minutes each. The procedures are described below. Some procedures will be carried out 3 times, each time in a different session so we can evaluate how reliably the measures can be taken. If you agree to participate in the study, the following will occur:

- A researcher will meet with you at the Van der Veer Institute and you will have an opportunity to have any questions answered. After signing the consent form, you will be asked to complete a generic questionnaire to ensure inclusion criteria are met and risks are minimised.
- You will be seated in a comfortable chair in an examination room at the Van der Veer Institute.
- Ultrasound measurements will be taken. Ultrasound is non-invasive procedure that allows us to measure the size of your swallowing muscles and to visualize how they work during swallowing.
- You will be asked to perform eight different tasks (as described below). Tasks 1-4 will be presented together but you will be performing them in no particular order. Tasks 5-8 will be presented together but you will be performing them in no particular order.
 1. Jelly will be put on the ultrasound imaging device (transducer) and this will be lightly placed on the skin under your chin to allow imaging of the muscles. You will be asked to remain still while five images of the muscles under your chin will be taken.
 2. The ultrasound imaging tool will be lightly placed under your chin. You will be asked to swallow your saliva. This will be repeated five times.

3. A head stabilising unit with two arms will be placed in front of you. One arm will stabilise the imaging tool and one arm will stabilise your head. You will be asked to bite soft putty in order to have an impression of your teeth so the exact same head position will be maintained during the assessment. The putty will be shaped in a U curve. It will be placed on a U shape plastic mould that will be inserted into the arm on the head stabilising unit. You will be asked to bite into the putty during the ultrasound procedure in order to remain still. Jelly will be put on the ultrasound's imaging tool and this will be lightly placed under your chin by adjusting the stabilising unit. You will be asked to remain still while five images of the muscles under your chin will be taken.
4. A head stabilising unit with two arms will be placed in front of you as described in task 3. The ultrasound imaging tool will be lightly placed under your chin by adjusting the stabilising unit. You will be asked to swallow your saliva. This will be repeated five times.
5. The ultrasound imaging tool will be lightly placed under your chin. You will be asked to swallow 10ml of water. This will be repeated five times.
6. The ultrasound imaging tool will be lightly placed under your chin. You will be asked to swallow very hard while squeezing your tongue in an upward and backward motion toward the soft palate. This will be repeated five times.
7. The ultrasound imaging tool will be lightly placed under your chin. You will be asked to swallow very hard (as described in task 6) while swallowing 10ml of water. This will be repeated five times.
8. The ultrasound imaging tool will be lightly placed under your chin. You will be asked to poke out your tongue as far and as comfortably as you can while holding it between your front teeth. Then you will be asked to swallow. This will be repeated five times.

When you have completed all these tasks you will be asked to repeat tasks 1-4, two more times in two more sessions. Again these tasks will be presented in a random order each time so you will not be performing them in the same order as you previously completed them.

Risks and Benefits

Ultrasound is a safe and non-invasive procedure that poses no physical risk. As you will be swallowing water there is the slight possibility of aspiration (the fluid going the wrong way and into the lungs), however this risk is no greater than swallowing other fluids or your own secretions throughout the day.

There are no direct benefits to you as an individual. You will be part of a study that contributes important information regarding treatment approaches and how to best use a tool used in swallowing research.

Confidentiality:

Research findings will be presented at international research meetings and submitted for publication in peer reviewed journals. Additionally, research findings will be made available to the local Canterbury medical community through research presentations and regional forums. However, no material which could personally identify you will be used in any reports on this study. Consent forms will be kept in a locked filing cabinet in the locked Swallowing Research Laboratory or will be stored on password-protected laboratory computers. Research data will be stored for a period of ten years after data collection is complete, at which time they will be destroyed. With your permission, data from this study may be used in future related studies, which have been given ethical approval from a Health & Disability Ethics Committee

Results:

If requested, you will be offered copies of the publications that arise from this research. However, you should be aware that a significant delay may occur between completion of data collection and completion of the final report. Alternatively, or in addition, you can choose to have the results of the study discussed with you personally by the lead investigator.

Compensation:

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the 2002 Injury Prevention Rehabilitation and Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are an earner or non-earner. ACC usually provides only partial

reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators.

If you have any questions about ACC, contact your nearest ACC office or the investigator.

Questions:

You may have a friend, family, or whanau support to help you understand the risks and/or benefits of this study and any other explanation you may require.

Please contact the primary researcher, Corina Winkelman, if you require any further information about the study. Corina can be contacted during work hours at (03) 378-6068 or after hours on 021 027 18815.

If you need an interpreter, this can be provided.

If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact an independent health and disability advocate: Free phone: 0800 555 050 Free fax: 0800 2 SUPPORT (0800 2787 7678) Email: advocacy@hdc.org.nz

This study has received ethical approval from the Central Regional Ethics Committee. Ethics reference number: CEN/10/05/020